RAC/M/44/2018
Final
24 May 2018

Minutes of the 44th Meeting of the Committee for Risk Assessment (RAC 44)

27 February started at 14.00
2 March suspended at 13.30
6 March resumed at 9.00
9 March ended at 12.00

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 44th meeting of the Committee for Risk Assessment (RAC 44). Apologies were received from three Members.

He noted that since the last RAC meeting of 2017, the CLP workplan had been updated and there are 55[1] CLP dossiers on the agenda for 2018 (up 20 from a five year average of 35). CLP is therefore very clearly the theme for 2018 and where possible will be placed in separate meeting weeks on the agenda.

The Chairman then reminded the Committee of the three dossiers on Occupational Exposure Limits for agreement at this meeting, noting the valuable comments received from members and encouraging others to read the opinions carefully if they had no done so already.

The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed once no longer needed. He added that the recordings from the 43rd meeting had already been destroyed. The Chairman noted that the minutes are adopted and they have been uploaded to S-CIRCABC and published on the ECHA website. The minutes include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting (RAC/A/44/2018). It was noted that agenda point 10.3.b Review reports, is for discussion only.

The agenda and the list of all meeting documents, including conclusions and action points are attached to these minutes as Annexes I and II (part IV) and part II, respectively. No points were raised under any other business.

3. Declarations of conflicts of interests to the Agenda

The Chairman requested all participants to declare any potential conflicts of interest to any of the agenda items. 15 Members declared potential conflicts of interest, each to specific agenda items, the majority related to concurrent employment of Members at agencies submitting dossiers to RAC but who had not been involved in the preparation. In the event of a vote, these Members were requested to refrain from voting on the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. Where Members declared that they had contributed to the preparation of a substance dossier for consideration by RAC, or similar potential conflict, they were asked to refrain from voting and the Chairman noted that he would consider additional mitigation measures. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

The Chairman declared an interest in the CLP dossier on lactic acid (AP 8.2.B.13), having authored one of the publications cited and informed the Committee that following the relevant Executive Director's Decision, Pilar Rodrigues-Iglesias would chair this agenda point.

4. Appointment of (co-) rapporteurs

[1] At the time of publication updated to 63.

a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95 (3) requests and Article 77 (3) (c) requests.

The Secretariat informed the Committee about a new electronic format (using 'EUSurvey') for collecting members' expressions of interest to volunteer as Rapporteurs. Some members expressed their concerns as to the level of information provided with the electronic list namely for the CLH intentions. In addition, they pointed out that for planning and coordination purposes they would prefer to have an overview of the preferences of their fellow Members. It was also pointed out that CLP had not in fact used a pool system for volunteering, unlike Restrictions and Authorisations which had this built into the process; this was acknowledged by the Secretariat.

The Secretariat will further work on the system to accommodate RAC preferences and the members will be informed about progress. The call for volunteers for the CLH dossiers / intentions will be extended.

In the closed session, the Committee agreed upon the proposed pools of the Rapporteurs for the forthcoming applications for Authorisation and for the Restrictions proposals.

5. Report from other ECHA bodies and activities

a) Report on RAC-43 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that all action points from the previous meeting RAC-43 had been completed. The summary of all consultations, calls for expression of interest in rapporteurships and written procedures (room document RAC/44/2018/02) is available in the usual meeting document on S-CIRCABC (see Annex IV). The slides regularly prepared to update the Management Board on ECHA activities will be forwarded to members when available after MB-49.

The Chairman also informed the Committee that the final minutes of RAC-43 had been adopted via written procedure and were uploaded to S-CIRCABC and are published on the ECHA website, and thanked those Members who had provided comments on the draft.

b) RAC workplan for all processes

The Chairman informed the meeting participants about the updated RAC work plan for Q1-4/2018, covering the four processes of Restriction, Authorisation, Harmonised Classification and Labelling of substances and evaluation of occupational exposure limits (Article 77(3)c requests). He informed Members that they could find the expected schedules for Restriction dossiers and Authorisation dossiers in the work plan. In addition, the scheduling to be considered for each Harmonised Classification and Labelling (CLH) dossier are given in the relevant section. The schedule of evaluations of occupational exposure in 2018 will be updated pending further requests from the Commission.

c) General RAC procedures

The Chairman informed the meeting that the three years term of the co-opted members in RAC and SEAC expires in September 2018. From ECHA's point of view, their contribution to the work of the Committee has been very valuable. The anticipated workload in the coming years justifies

maintaining additional specialist capacity. In the interest of transparency, ECHA has chosen to use an open call to select candidates for all 10 co-opted places in RAC and SEAC.

The Chairman invited the Members to agree on the draft proposal for co-opting additional Members (document RAC/44/2018/03), which confirms the selection procedure and the required competences.

RAC agreed on the selection procedure as proposed by the Secretariat and on the required competences, with the addition of a further suggestion to add 'exposure modelling' to the list.

6 Requests under Article 77 (3)(c)

6.1 General occupational exposure issues

a) Feedback from the preparatory workshop

The Secretariat presented a summary of the rapporteurs preparatory workshop noting that it had started with a presentation by DG Employment on the legal framework the procedure for developing EU OELs and, followed by two presentations by RAC-members on the concept of application of Assessment Factors in deriving OELs and the concepts of the Limit Values for STEL, BGV and BLV respectively.

The discussion focussed on the reasoning for the need for a Mode of Action based threshold. It was acknowledged that for setting a threshold level for carcinogens, knowledge is needed on the Adverse Outcome Pathway/MoA. The comparison of assessment factors for "classical" threshold effects and carcinogens (with a threshold) was discussed. Some members suggested to apply a severity factor (e.g. steepness of the dose response) to address remaining uncertainty of cancer risk, taking into consideration the inter-dependence of the sequence of effects in setting such severity factors. Double counting with other assessment factors should be avoided. Furthermore, it was discussed how to use human experience/epidemiological data in OEL derivation. Finally, members concluded that a MoA based threshold should be possible on a case by case basis for a limited number of substances.

The second part of the discussion focused on the Biological Guidance Values (BGVs) and the Biological Limit Values (BLVs). It was concluded that BGVs and BLVs are not required by worker protection legislation but usually provided by SCOEL for Chemical Agents Directive (threshold) cases and for Carcinogens and Mutagens Directive (only BGV, if a non-threshold substance), amongst other reasons to highlight the importance of biomonitoring. These values can only be provided in some cases where biomonitoring is feasible. A BGV (or Biological Reference Value) is a statistically derived level in occupationally unexposed populations (sometimes also general population surveys can be used for BGV setting, but may include occupationally exposed people) and can vary regionally. The BLV is a health based occupational limit and for bioaccumulative substances or substances with low vapour pressure and high potential for skin exposure, may provide a better measure of exposure (e.g. in one case SCOEL has provided only BLV and not an OEL).

Members considered that where RAC (or SCOEL) had determined a Mode of Action-based threshold for a genotoxic carcinogen, it might also be possible to derive a BLV if appropriate. RAC has examined the available information for the OEL cases requested by the Commission and in some cases RAC made proposals for BGV and/or BLV.

b) Future of CMD/CAD and the possible setting up of an occupational exposure working group

The Chairman informed RAC of ECHA's considerations on managing scientific evaluations related to chemical exposure in the workplace. He noted that with this meeting, the Pilot project on developing five Occupational Exposure Limits at the request of the Commission would be completed. He informed that there was no further information at this time as to the Commissions wishes but referred members to the Commissions REACH review and the accompanying Communication which had been published on 5 March 2018 as providing some indications. He also noted that a further peak in REACH authorisations was expected in 2019/20 and that supporting this work in terms of capacity and expertise needed to be considered together with OEL evaluations as some of the expertise needed overlaps.

One possibility going forward was to set up a working group with terms of reference from RAC. He noted that this could involve either or both of the above processes and that the Secretariat was exploring the best options at present. Members were generally positive, noting that a working group could strengthen knowledge of occupational health issues, could be used to involve additional expertise and be more inclusive of worker protection interests. It could also serve to reduce debating time in RAC plenaries. The members encouraged ECHA to explore this proposal further. One member pointed out that a complex OEL discussion often involves several meetings and while this needs to be efficient, more room for preparation of opinions may be needed than currently available in RACs schedule. The Secretariat agreed to keep RAC informed of any developments.

6.2 Occupational exposure- opinion development

The Chairman informed the Committee that following a request from the Commission, the Executive Director had requested RAC[2], on the basis of proposals provided by ECHA, to draw up opinions on "the evaluation of the scientific relevance of occupational exposure limits (OELs)" for **nickel and its compounds, acrylonitrile and benzene**. The aim of the opinions is to provide scientific advice in support of the Commission action on amending Directive 2004/37/EC on the protection of workers from the risk related to exposure to carcinogens and mutagens at work (CMD) (4th amendment). This advice must include a recommendation to be given to the Advisory Committee on Safety and Health at Work (ACSH) in line with the relevant OSH legislative procedures and in the format used by SCOEL in drafting its opinion. The Chairman reminded the participants that the deadline for forwarding the RAC-opinions to the Commission is 26 March 2018.

An interim Committee working procedure on the evaluation of OELs in support of CMD Directive following the Article 77.3.c. requests was developed to make the roles and responsibilities of ECHA and RAC clear as well as the procedural steps to complete the task and was agreed at RAC-42 and published on ECHA's website.

a) Nickel and its compounds

The Chairman welcomed the industry expert accompanying the regular stakeholder observer Eurometaux and an occasional stakeholder from CONCAWE.

The Chairman reminded the Committee that the second draft opinion and the draft ECHA proposal on nickel and its compounds were discussed at RAC-43. The final draft opinion and the

[2] Mandate of 12 May 2017

Background Document, i.e. the revised ECHA proposal, were made available on 30 January for RAC members' comments.

The Chairman informed the Committee that the request from the European Commission is related to Nickel and its compounds~~,~~ which refers to all nickel compounds, incl. organic and inorganic substances but that the main focus was on the inorganics.

At RAC-43 the Committee had supported the proposed Mode of Action-based threshold approach and also a common occupational exposure limit for the different nickel species, which includes one OEL for respirable and another OEL for inhalable particles to address lung cancer and toxicity, and lung and nasal cancer, respectively.

The focus of the discussion was on the justification for the different assessment factors for the respirable OEL, further explanation on the use of Human Equivalent Concentration (HEC) calculation, and a conclusion on the respirable and inhalable OELs.

RAC agreed to apply assessment factors (AFs) to extrapolate the animal data to humans for the calculation of OELs for both the respirable fraction and the inhalable fraction.

Regarding the **respirable OEL**, the following AFs were applied: since the HEC calculation was included, there was no need for a further AF for toxico-kinetic differences; also an AF of 1 is considered sufficient to cover for toxico-dynamic differences since comparison between human and rat data did not show that humans were more sensitive to the carcinogenic effects than rats; for intra-species variability an AF of 3 was applied and finally, an additional AF of 2 was applied for nickel compounds for the severity of the toxic endpoint (cancer).

Regarding the **inhalable OEL**, a standard AF of 3 was used for the LOAEC to NOAEC extrapolation and a correction factor of 2 for recognised historical changes in sampler efficiency was also applied; no additional AFs for inter-individual variation was considered to be needed because the most conservative estimate on the cancer risk among several human cohorts are considered to adequately address the variability among workers.

RAC concluded on an OEL of 0.005 mg Ni/m^3 for the respirable fraction of both nickel metal and nickel compounds and concluded on an OEL of 0.03 mg/m^3 for the inhalable fraction of nickel compounds. Furthermore RAC considered the uncertainties, in particular the risk of remaining genotoxic effects and concluded that at exposures below these mode of action based thresholds, no significant residual cancer risk is expected.

The Committee adopted its opinion on occupational exposure limits (OELs) for nickel and its compounds by consensus. The Rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the adopted RAC opinion and to ensure that the supporting documentation (Background Document and Responses to comments from the public consultation) is in line with the adopted RAC opinion. The Chairman thanked the Rapporteurs for their efficient and thorough handling of this challenging proposal on occupational exposure limits, the Committee Members and the stakeholders for their contributions.

b) Benzene

The Chairman welcomed the industry expert accompanying regular stakeholder observer Cefic and an occasional stakeholder from CONCAWE, accompanied by an expert.

The Chairman reminded the Committee that the second draft opinion and the draft ECHA proposal on benzene were discussed at RAC-43. The final draft opinion and the Background Document, i.e. the revised ECHA proposal, were made available on 30 January for RAC members' comments. In response to these comments a new version of the final draft opinion was made available on 22 February.

The rapporteurs presented the justification for a mode of action-based threshold for chromosomal damage to be used in the establishment of the OEL at ≤ 0.05 ppm instead of ≤

0.1 ppm, which latter was discussed at RAC-43. The focus of the discussion was on the weight of the available evidence to derive an OEL for benzene based on genotoxic (clastogenic and aneugenic) and haematotoxic effects observed in workers and any potentially remaining uncertainties below the proposed OEL.

RAC considered that a mode of action based threshold for benzene based on clastogenic and aneugenic effects could be established, following the weight of evidence from a wide range of data in benzene exposed workers.

The RAC-members supported the proposed WoE-based LOAEC of 1 ppm for clastogenicity and aneugenicity in peripheral blood lymphocytes and sperm and the assignment of assessment factors (AFs) for uncertainties. It was agreed to use an overall AF of 20, including AF of 2 for intraspecies variability (due to the generally small groups of workers investigated) and an AF of 10 for dose-response and severity. By applying such AFs, an OEL of 0.05 ppm resulted. Studies investigating clastogenic effects in small groups of workers below 1 ppm provided indications for a NOAEC in the range of ≤ 0.1 ppm and hence support an OEL of 0.05 ppm.

RAC members supported that the limit so derived, will avoid exposures that induce chromosomal damage in workers, is considered to have no significant residual cancer risk.

The rapporteurs noted that results from animal studies with a LOAEC of 1 ppm for clastogenic effects in the bone marrow following the the application of appropriate AFs also supported an OEL below 0.1 ppm.

With respect to haematotoxicity, a variety of studies with thousands of workers overall from different work environments have been reviewed. Considering their weight of evidence, a LOAEC of 2 ppm and a NOAEC in the range of 0.5 ppm were derived. RAC supported the rapporteur's proposal that there is no need to derive an OEL for haematological effects, since the recommended OEL of 0.05 ppm based on clastogenicity and aneugenicity will protect workers also for haematotoxicity.

RAC members supported the proposed biological limit value and the biological guidance values, the recommendation for no STEL and the recommendation to maintain the 'skin notation' for benzene.

The Committee adopted its opinion on the evaluation of the scientific relevance of occupational exposure limits (OELs) for benzene by consensus. The Rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the adopted RAC opinion and to ensure that the supporting documentation (Background Document and Responses to comments from the public consultation) is in line with the adopted RAC opinion. The Chairman thanked the Rapporteurs and the members for their efficient and thorough evaluation of this proposal on occupational exposure limits, and the stakeholders for their contributions.

c) Acrylonitrile

The Chairman welcomed the industry expert accompanying a regular stakeholder observer, an occasional stakeholder from CONCAWE and the ECHA contractors (via WebEx).

The Chairman reminded the Committee that the second draft opinion and the draft ECHA proposal on acrylonitrile were discussed at RAC-43. The final draft opinion and the Background Document, i.e. the revised ECHA proposal, were made available on 25 January for RAC members' comments. In response to these comments a new version of the final draft opinion was made available on 22 February.

The discussion focussed on the derivation of the mode of action based threshold limit value for carcinogenicity and the choice of assessment factors. The Committee agreed to derive a mode of action based threshold limit value of 1 mg/m^3 (0.45 ppm) by assigning an assessment factor of 2.5 for interspecies differences, a factor of 5 for intraspecies differences and a factor of 5 for

issues related to dose-response and severity of effects. Furthermore, the Committee agreed that below the mode of action based threshold no significant residual cancer risk is expected in workers. The Committee considered that this occupational exposure limit as 8 h TWA (OEL) will also be sufficiently protective against non-cancer effects, in particular nasal irritation and neurotoxicity. RAC members agreed to a revised limit value for these latter non-cancer endpoints, following comments received after RAC-43. RAC members also supported a biological limit value based on the agreed OEL.

The discussion on a short-term exposure limit (STEL) protective against irritation/neurotoxic effects (in addition to cancer effects) was reopened following comments received after RAC-43. RAC recommended a STEL of 4 mg/m^3 (1.8 ppm), corresponding to four times the OEL.

The Committee adopted its opinion on the evaluation of the scientific relevance of OELs for acrylonitrile by consensus. The Rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the adopted RAC opinion and to ensure that the supporting documentation (Background Document and Responses to comments from the public consultation) is in line with the adopted RAC opinion. The Chairman thanked the Rapporteurs for their efficient and thorough handling of this proposal on occupational exposure limits, the Committee Members and the stakeholders for their contributions.

7. Requests under Article 95(3)

None

8. Harmonised classification and labelling (CLH)

8.1 General CLH issues

The Secretariat informed the Committee about the extension of CLH public consultations form 45 to 60 days. The purpose being to allow more time for parties concerned to prepare and submit their comments and also to align it with the duration of the European Food Safety Agency (EFSA)'s public consultation on draft assessment reports or renewal assessment reports for active substances in plant protection products.

In addition, the Secretariat informed the Committee about changes in the dissemination of information during the development of CLH opinions. The aim of these changes being mainly to increase the transparency of the process, to allow MSCAs, especially Dossier Submitters, to better follow the progress of the (written) discussion for a particular substance and to provide information to all parties in a timely manner.

8.2 CLH dossiers

A. Hazard classes for agreement without plenary debate[3] (see section B below for hazard classes form the same substances debated in plenary)

RAC reviewed an 'A-listing' of hazard classes for a range of substances and being informed by the Secretariat of the appropriate scrutiny by Rapporteurs and commenting RAC Members in each case, agreed these without plenary debate. The details for each substance are given below in section B.

[3] Following adequate scrutiny by the Rapporteur and commenting Members and taking the comments from the Public Consultation into account, selected hazard classes are proposed for agreement through a list ('fast-track') without further debate in the Committee.

B. Substances with hazard classes for agreement in plenary session

1) octamethylcyclotetrasiloxilane; [D4]

The Chairman reported that D4 is used to produce silicone polymers, as an intermediate in the production of other organosilicones. It has a wide range of industrial uses but is also applied in personal and household care products where it is used as a solvent for other larger molecules.

The substance has a harmonised classification and labelling entry in Annex VI of the CLP Regulation as Repr. 2; H361f*** and Aquatic Chronic 4; H413. The Dossier Submitter (DE) proposed to modify the environmental classification to Aquatic Chronic 1; H410, with a Multiplying (M) factor of 10.

The Committee concurred with the DS proposal and noted that no effects were seen in the acute toxicity studies.

During the discussion on the aquatic chronic toxicity an expert accompanying Cefic disagreed with the DS claiming that a weight-of-evidence based approach should, instead, be followed by the Committee referring to the "unique" physical-chemical properties of the substance. In response to this argument, a RAC member noted that the conclusion of the DS and the RAC Rapporteurs are consistent with previous discussions in the ECHA MSC for this substance on its PBT/vPvB status and that the same data has been included in the REACH Registration dossier.

RAC agreed to classify D4 as Aquatic Chronic 1; H410 (M=10) by consensus.

The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

2) branched hexatriacontane

The Chairman reported that branched hexatriacontane, an alkane, is used in synthetic automotive and industrial lubricants. The substance has an existing entry in Annex VI of the CLP Regulation with a classification as Aquatic Chronic. 4; H413. The legal deadline for the adoption of an opinion is 9 August 2018.

The DS (UK) proposed to remove the current classification based on the absence of chronic toxicity and low potential to bioaccumulate using information from read-across and other model-based evidence.

The Committee agreed to remove the classification for Aquatic Chronic 4; H413 based on the absence of chronic aquatic toxicity, as manifested by NOEC values above water solubility for analogue substances.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

3) 2-methoxyethyl acrylate

The Chairman reported that 2-methoxyethyl acrylate is an industrial chemical used as an intermediate and in the production of chemicals, rubber products and plastic products. The substance has no existing entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 30 August 2018.

The DS (FR) proposed to classify the substance for the following hazards: Flam Liq. 3; H226, Acute Tox. 4; H302, Acute Tox. 3; H331, Skin Corr. 1C; H314, Eye Dam. 1; H318, Skin Sens.

1; H317, Muta. 2; H341, Repr. 1B; H360FD and to add the supplemental hazard information EUH071 (corrosive to the respiratory tract). The DS additionally proposed no classification for STOT RE and respiratory sensitisation.

The following hazard classes were agreed via the fast-track procedure, with scrutiny but without plenary debate:

- Flam. Liq. 3; H226
- acute dermal toxicity – no classification
- Acute Tox. 4; H302, oral ATE = 404 mg/kg bw
- Acute Tox. 3; H331, inhalation ATE = 2.7 mg/l
- Skin Corr. 1C; H314
- Eye Dam. 1; H318
- Skin Sens. 1; H317
- Resp. Sens. – no classification.

Taking into account the effects observed in the acute inhalation study and the general corrosive properties of 2-methoxyethyl acrylate in combination with a high vapour pressure, RAC agreed that the conditions to add the EUH071 were fulfilled.

As regards toxicity to reproduction, the Committee concurred with the Dossier Submitter and agreed to classify 2-methoxyethyl acrylate into category 1B for both fertility and development, based on dose-related effects on fertility (histopathological changes in testes and epididymis at all dose levels) and on development (decreased live litters and decreased viability index) observed in the combined oral repeated dose toxicity study with the reproduction/developmental toxicity screening test in Wistar rats (OECD 422)

In addition, the main primary metabolite of 2-methoxyethyl acrylate (2-methoxyethanol) has a harmonised classification as Repr. 1B; H360FD.

Regarding germ cell mutagenicity, genotoxic potential was shown in two in vitro tests (mouse lymphoma assay +/- metabolic activation, and human lymphocytes chromosomal aberrations + metabolic activation) and positive effects were seen in an in vivo comet assay in the rat forestomach (humans do not possess a forestomach, but a comparable epithelium exists at sites of initial contact). The result in liver was negative and in glandular stomach equivocal.

One RAC member suggested that another type of study would have been preferable with a cytotoxic substance (i.e. an in vivo micronucleus test) which could have overcome the potential interference of cytotoxicity for this (skin) corrosive substance, this being a known weakness of the Comet assay. RAC noted that many more Comet assays could be expected from testing proposal decisions.

The Committee concurred with the Dossier Submitter and agreed to classify 2-methoxyethyl acrylate as Muta 2; H341.

RAC agreed that in the absence of standard 28-day or 90-day repeated-dose toxicity studies there was insufficient evidence to conclude on the classification for STOT RE.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

4) diisooctyl phthalate

The Chairman welcomed the experts accompanying the Cefic and EuPC stakeholder observers and reported that DIOP is an industrial chemical primarily used as a plasticiser for synthetic rubber and vinyl, cellulosic and acrylate resins in a variety of consumer products (note: based

on industry input DIOP was de-commercialized in Europe in 1994 and is no longer produced commercially outside the EU either). It has no existing entry in Annex VI to the CLP Regulation and there is no REACH registration dossier. The legal deadline for the adoption of an opinion is 30 August 2018.

The DS (FR) proposed to classify DIOP for toxicity to reproduction (Repr. 1B; H360FD).

RAC agreed to classify the substance in category 1B for developmental toxicity based on statistically significant increases in embryo and foetal lethality, including post-implantation losses and resorptions and decreased pup survival at 1 000 mg/kg bw/d in experimental animal studies. In addition, permanent post-natal changes in the male reproductive system (hypospadias, marked underdeveloped seminal vesicles, undescended testis, hypospermatogenesis and retained nipples) in the high dose group were observed. The effects were reported in the absence of marked maternal toxicity. It was also noted that these effects have been seen with other phthalates which have carbon backbones in the alkyl side-chains in the range of C3-C6 i.e. covering DIOP which has mainly C6 backbones in the alkyl side chains.

In the discussion about fertility impairment it was noted that there was no reliable study assessing sexual function and fertility available on DIOP itself. A two-generation reproductive toxicity study in mice was mentioned in the CLH report, but only a summary of the study was available. Industry commented that this study was performed with DEHP and not DIOP[4]. However, due to the uncertainty on which substance was tested and due to the limited data available, this study was not taken into account by RAC in the classification. It was further noted that the proposal from the DS was based on effects on reproductive organs induced during foetal development, but shown to persist in animals postnatally up to adult age. The effects seen on reproductive organs in developing animals were similar to those seen in adult animals for other phthalates with carbon backbones of C3-C6 in the alkyl side chains i.e. similar to DIOP (and having a harmonised classification as Repr. 1B for fertility). The question arose as to whether this argument could be used for classification for fertility, as it had already been used to classify DIOP for developmental toxicity.

In the CLH proposal, a category approach was also proposed, including phthalates with a side chain length of C3 to C7. However, Industry pointed out during the discussion that DIOP should be regarded as belonging to C3-C6 phthalates as it commonly includes mainly (70-75%) isomers with C6 ester backbone and less than 25% of isomers with C7 backbone. Industry requested that the draft opinion on DIOP and the draft Background Document be revised, where appropriate, correcting references to "C3-C7 backbones" to "C3-C6 backbones". Industry also pointed out that the Saillenfait et al (2014) paper supports that phthalates with C3-C6 backbones in the alkyl side chains are reprotoxic. Since no study assessing sexual function and fertility was available, RAC supported the classification of DIOP based on read across from DEHP specifically (DEHP is a C6 carbon backbone substance with total carbons of C8 in the alkyl side chains). Based on this the Committee agreed to classify DIOP in category 1B for fertility effects.

RAC further assessed the need for a specific concentration limit. It was agreed that based on ED_{10} values DIOP would fall into the low potency group, but due to the modifying factors included in the assessment of SCL it was decided that the generic concentration limit should rather be applied.

[4] RAC was informed that the source referred to a tertiary reference, i.e. the HSDB, which cited the (US) HPV report as the secondary reference and which in turn included the reference to the primary study (Lamb, et al., Toxicol.Appl. Pharm., 1987, Vol.88, pp.255-269), which indeed states that the oral study in mice was done on DEHP and three other (diethyl, di-n-butyl and di-n hexyl) phthalates.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

5) imiprothrin (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that imiprothrin (ISO) is used as a biocidal active substance for controlling insects, such as cockroaches and other crawling insects. The substance has an existing entry in Annex VI of the CLP Regulation with the classifications as Acute Tox. 4*; H302, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The legal deadline for the adoption of an opinion is 15 August 2018.

The DS (UK) proposed to classify the substance for acute toxicity (modify Acute Tox 4; H302 and add Acute Tox. 4; H332, with oral ATE=550 mg/kg bw and inhalation ATE=1.4 mg/L), toxicity to reproduction (Repr. 2; H361d) and add an M-factor of 10 to aquatic acute and aquatic chronic classifications (Aquatic Acute 1; H400, M=10 and Aquatic Chronic 1; H410, M=10).

The following hazard classes were agreed via fast-track procedure, with scrutiny but without plenary debate:

- Acute Tox. 4; H302 (oral ATE=550 mg/kg bw)
- Acute Tox. 4; H332 (inhalation ATE=1.4 mg/L)
- Acute toxicity via dermal route – no classification
- STOT RE – no classification
- Germ cell mutagenicity – no classification
- Aquatic Acute 1; H400 (M=10)
- Aquatic Chronic 1; H410 (M=10)

Thus specific target organ toxicity – single exposure (STOT SE), carcinogenicity and reproductive toxicity were discussed at the plenary meeting.

Regarding STOT SE, the Committee discussed relevance for humans and the dose levels of effects occurring, in light of the already agreed classification for acute toxicity. RAC however supported additional classification with STOT SE 2; H371 for the nervous system, based on the consistent signs of neurotoxicity occurring also at non-lethal doses in acute oral and inhalation studies. The Committee further noted that imiprothrin is a pyrethroid, which is a group of substances known to have neurotoxic properties based on a common mode of action.

RAC discussed the increase in lung adenocarcinoma as there were incidences outside of the historical control range (HCR), but were observed only in male mice. The uncertainty regarding the maximum tolerated dose (MTD) being exceeded was acknowledged and members noted that further data on the body weight (gain) of animals with tumours would clarify the health status and confirm data suitability for evaluation. This information was not available in the dossier and RAC considered the MTD as not exceeded taking into account only moderate suppression of body weight at mid and high doses and no effect on survival in male mice. RAC agreed on category 2 classification for carcinogenicity (H351) considering dose-related increase in lung adenocarcinoma in male mice, incidences at mid and high doses above HCR and incidences expressed in one species and one sex only.

The Committee concurred with the DS and agreed not to classify for fertility and lactation due to the absence of adverse effects on fertility parameters in a 2-generation rat study and not meeting the criteria for lactation due to either no effects observed or lack of data. The DS proposed to classify developmental toxicity in category 2 based on the finding of fusion of the nasal bone (considered a malformation) in a rabbit developmental study. RAC however considered classification not warranted given the total weight of evidence (the fusion was only

partial, no other fusion of craniofacial bones or malformations found, and the marked maternal toxicity observed at the top dose).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

6) silicon carbide (fibres fulfilling the WHO definition: diameter <3 µm, length > 5 µm and aspect ratio ≥ 3:1)

The Chairman welcomed the expert accompanying the Cefic stakeholder observer and reported that silicon carbide (SiC) fibres are substances differing in their form (size and shape) and included SiC whiskers, crude and grains; these are used in ceramic, refractory and foundry industries. The legal deadline for the adoption of an opinion is 2 August 2018.

SiC fibres fulfilling the WHO definition (WHO, 1985; diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) have no existing entry in Annex VI of the CLP Regulation.

The DS (NL) proposed to classify all forms (SiC fibres, SiC whiskers and SiC cleavage fragments) fulfilling the WHO fibre definition as Carc. 1B (H350i) for carcinogenicity via the inhalation route of exposure. The proposal is based mainly on animal data. Observations in workers in the SiC industry after occupational dust inhalation in Norway, published in 2001-2012 and referred to in the CLH report were considered by RAC to be of lower importance due to a number of uncertainties (co-exposure to other potentially carcinogenic substances as dust components and relatively short period of observations).

RAC briefly discussed fibre carcinogenicity and the mechanistic aspects of tumour development, acknowledging that lung carcinogenicity of fibres is a function of the dimensions of the fibres (length, diameter and aspect ratio), dose (fibre concentration) and durability (biopersistence of fibres).

The IND expert accompanying the Cefic stakeholder observer pointed out that their preference would be to differentiate clearly among the different forms of fibres, especially since SiC whiskers are not produced intentionally and do not appear in their products. In response the RAC Rapporteur noted that the scope of the entry is clearly defined by the size (diameter <3 µm, length > 5 µm and aspect ratio ≥ 3:1) whereas any other definition / specification would be less accurate, because SiC fibres / whiskers / fragments are not strictly defined by their size (i.e. it cannot be excluded that SiC fibres contain a particular percentage of whiskers).

Based on the evidence from the inhalation carcinogenicity studies in rats (lung carcinomas and mesotheliomas with a potency for inducing mesothelioma higher than amosite asbestos at comparable concentrations) and on intraperitoneal and intrapleural carcinogenicity instillation studies in rats (tumour rates equivalent to or higher than for chrysotile B) and on supporting evidence (inflammation, fibrosis and precursor lesions) from a repeated inhalation study in rats, the Committee agreed to classify silicon carbide fibres (diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) as category 1B for carcinogenicity.

RAC agreed that based on the present scientific knowledge, routes of exposure other than inhalation were unlikely; in addition, RAC concurred with the DS proposal that no fibre-specific notes (A, Q, R) are applicable for silicon carbide fibres (diameter <3 µm, length > 5 µm and aspect ratio ≥ 3:1).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

7) granulated copper

The Chairman reported that Granulated copper is a form of copper metal defined by its particle size and specific surface area. Granulated copper particles are cylindrical with a length greater than 1 mm (range: 0.9 – 6.0 mm; mean: 2.1 mm) and width below 1 mm (range: 0.494 – 0.949 mm; mean: 0.706 mm), and a surface area of around 25.6 cm^2/g (significantly above the limit for massive). As such, it is considered to lie between massive (defined as a sphere with a diameter > 1 mm and a surface area of < 6.74 cm^2/g) and powder form (diameter of < 0.2 mm and a surface area of 240 cm^2/g) of copper. Granulated copper is intended to be used as a biocidal active substance in wood preservative products (PT8) and is restricted to industrial use only, in timber treatment plants operated by trained personnel.

It has no existing entry in Annex VI of the CLP Regulation. Moreover, there is currently no existing harmonised entry for copper metal (be it in massive or powder form). The legal deadline for the adoption of an opinion is 15 August 2018.

The Dossier Submitter (FR) proposed to classify the substance as Eye Irrit. 2; H319 and Aquatic Chronic 2; H411.

The following hazard classes were agreed via fast-track procedure, with scrutiny but without plenary debate:

- Physical hazards – no classification,
- Skin corrosion / irritation – no classification,
- Skin sensitisation – no classification
- STOT SE – no classification,
- STOT RE – no classification,
- Germ cell mutagenicity – no classification
- Carcinogenicity – no classification
- Toxicity to reproduction – no classification

The rapporteurs proposed to discuss acute toxicity, eye irritation and environmental hazards at the plenary meeting.

The Chairman clarified that the classification proposal applies to the specific form of the metal (i.e. granules). The proposal fulfils the requirements of the BPR where a classification proposal should be submitted for the specific size range as used in the biocidal product and follows the provisions under CLP, Article 36(2) and the secretariat confirmed this.

RAC agreed with the DS proposal not to classify granulated copper for acute toxicity (any route). For the dermal route, no hazard would be expected given that 10 other copper compounds that were previously evaluated by RAC were not acutely toxic via this route, irrespective of their degree of solubility. Since particles of this specific grain-size are not inhalable, RAC supported no classification for the inhalation route. However, regarding the justification for no classification for acute oral toxicity RAC did not agree with the DS proposal to read across from copper flakes in combination with in vitro bio-elution data on various copper compounds. Therefore, RAC agreed for no classification for acute oral toxicity based on insufficient data.

Contradictory to the DS proposal for Eye Irrit. 2; H319 the Rapporteurs propose no classification, based on absence of relevant data. RAC members considered that the proposal by the DS to read-across from coated copper flakes was not justified given the specific form and particle size of granulated copper. Some RAC members suggested not to classify based on read across to copper oxide (not classified), but others considered this unjustified due to lack of further

information. RAC agreed to no classification due to insufficient data but recognised that the testing of such solids for eye irritation may have issues related to physical stress and could be impracticable.

Concerning the DS's proposed environmental classification as Aquatic Chronic 2; H411, the Rapporteur raised several concerns on the selection of data (standard vs. non-standard species) in the dossier, the aggregation and the handling of data (e.g. use of geometric means, normalisation and hardness considerations), potential inconsistencies in the acute to chronic ratios of aquatic toxicity data as well as the lack of justification for extrapolation of T/Dp data for loadings lower than 1 mg/L. It was also recognised that the database is exceptionally large but the least data are available at acidic pH, at which copper is proven to be most toxic. He noted that there were many open questions to be answered in order to complete the evaluation.

In the following discussion, the DS provided clarifications on the main issues raised by the Rapporteur and referred to the information having very recently been provided in writing to RAC upon request by the Rapporteur. Their approach was aimed to ensure consistency amongst different assessments (VRAR, 2008 and previous RAC opinions adopted on copper compounds in 2014) and that it follows the CLP guidance and legal requirements. The Chairman thanked the DS for their clarifications and contributions and at the same time underlined that the work of the Rapporteurs and RAC is to assess the proposal submitted and potential comments received during PC.

The representative by Eurometaux emphasised that the DS in their analysis had considered the most important factors which affect copper toxicity to aquatic organisms, i.e. DOC and pH. Moreover he pointed out that analysis of species sensitivity distributions, availability of fish data or additional information on rapid removal was not presented in the submitted CLH dossier or provided during PC and it is not appropriate to add those at this stage of the process. Furthermore he highlighted that for large databases, unbounded values should not be used and referred to past discussions and conclusions on other metals and compounds, hence it is understood that there is no need re-open this discussion.

The Chairman noted that only three RAC members had commented on this opinion and underlined the importance that all RAC members with environmental science/ecotoxicology in their ECHA competence matrices should provide their comments during a second round of RAC consultation.

The Chairman summarised that RAC agreed on the human health classification of granulated copper. Further work on the proposal concerning the environmental classification will continue after analysis of the written clarification provided by the DS. The proposal for environmental classification is scheduled for discussion and adoption at the forthcoming RAC-45 in June 2018.

8) nitric acid...%

The substance originally had a harmonised classification and labelling entry in Annex VI of the CLP Regulation (Ox. Liq. 3; H272 and Skin Corr. 1A; H314 [Ox. Liq. 3; 272 C ≥ 65%, Skin Corr. 1A; H314 C ≥ 20%, Skin Corr. 1B; H314 5% ≤ C < 20%]). In 2012 the DS (DE) submitted a proposal to ECHA to supplement the current classification of nitric acid by adding a new classification as Acute Tox. 1; H330 (based on two studies using highly concentrated nitric acid) with the supplemental hazard information EUH071 (Corrosive to the respiratory tract) and a change of the current classification as Ox. Liq. 3 to Ox. Liq. 2; H272 for concentrated nitric acid (C ≥ 99%). RAC-24 agreed to this proposal, which was subsequently included into the 7th ATP

to the CLP Regulation, except for Acute Tox. 1. This classification was postponed, after Industry commented that there is a non-linear relationship between the nitric acid concentration and toxicity, with large consequences for the classification of nitric acid mixtures (containing < 70%) using the additivity formula.

In July 2015, the final report on the acute inhalation toxicity study in Wistar rats (4-hour vapour exposure, nose-only) with nitric acid 70% was submitted by industry, which is the basis for the current CLH dossier by DS.

Based on this data the dossier submitter proposed to split the exiting entry on "nitric acid …%" into the two following entries: (1) "nitric acid …% [C > 70%]" and (2) "nitric acid …% [C ≤ 70%]". While maintaining the previous Committee's agreement for > 70% nitric acid, it was proposed to instead classify ≤ 70% nitric acid as Acute Tox. 3; H331, ATE = 2.1 mg/L/4h, and with the additional labelling EUH071.

RAC agreed to assign the supplemental hazard information EUH071 (corrosive to respiratory tract) via fast-track procedure. The Committee also discussed the results of the acute inhalation toxicity study referred to above. RAC did however not conclude on the classification as the rapporteur questioned the timing of the euthanisation of several animals during the inhalation study which could also lead to Acute Tox. 2 being the more appropriate classification. The Committee requested the Secretariat through the German Competent Authority to seek clarification on the details of this study from the test laboratory. ECHA agreed to take this matter up and the RAC rapporteurs will revise the opinion as necessary, based on the information received. The Secretariat will schedule the dossier for a discussion at the RAC-45 plenary meeting in June 2018.

9) pymetrozine (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that pymetrozine (ISO) is an active substance used in plant protection products as an insecticide. The substance has an existing entry in Annex VI of the CLP Regulation for carcinogenicity and for environmental hazard (Carc. 2; H351 and Aquatic Chronic 3; H412). The legal deadline for the adoption of an opinion is 29 November 2018.

The DS (DE) proposed to retain the existing classification for carcinogenicity, to add classification for toxicity to reproduction (Repr. 2; H361fd) and to modify the environmental classification (Aquatic Chronic 1; H410, M=1).

The following hazard classes were agreed via the fast-track procedure:

- Physical hazards – no classification
- Aquatic Chronic 1; H410, M-factor =1.

RAC discussed the existing classification of pymetrozine for carcinogenicity in category 2 based on the available data i.e. two long-term toxicity and/or carcinogenicity studies and three mechanistic studies conducted in mice and rats. The mechanistic data available could not exclude the relevance of the liver tumours for humans or the mode of action of their induction in experimental animals. After a short discussion the Committee agreed to retain the classification in category 2 for carcinogenicity noting that the substance is non-genotoxic (confirmed by negative *in vivo* and *in vitro* tests).

As regards toxicity to reproduction, RAC agreed to classify pymetrozine into category 2 for fertility based mainly on consistent testicular toxicity in dogs supported by the findings in the rat.

For developmental toxicity, RAC supported the Dossier submitter in favour of a classification in category 2 based on the effects on displacement of pubic bones in rats (at 300 mg/kg) and rabbits (structural and skeletal anomalies at 75 and 125 mg/kg). In addition, RAC noted supporting findings in the neuro-developmental toxicity study in rats and the main developmental toxicity in rabbits (post-implantation losses and early resorptions).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

10) Margosa, ext. [cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide]

The Chairman reported that *Margosa extract* is a biocidal active substance approved for use as a repellent biocide (PT19). The substance has no existing entry in Annex VI of the CLP Regulation thus in accordance with Article 36(2) of CLP all hazard classes need to be assessed. The legal deadline for the adoption of an opinion is 15 June 2018.

The Dossier Submitter (DE) proposed no classification for any of the CLP hazard classes.

The following hazard classes were agreed via fast-track procedure:

- Acute toxicity via dermal and inhalation route – no classification
- Skin corrosion/irritation – no classification
- Skin sensitisation – no classification
- Single exposure (STOT SE) – no classification
- Serious eye damage/irritation – no classification
- Germ cell mutagenicity – no classification
- Carcinogenicity – no classification

RAC evaluation of physical hazards was not included in the first draft opinion before the RAC plenary meeting, so it was included in the revised first draft opinion and a slide was presented at the plenary. RAC concurred with the DS that classification for physical hazards is not warranted.

The remaining hazard classes, STOT RE 2 (skin, dermal), reproductive toxicity, acute toxicity via oral route and Aquatic Chronic 3; H412 were discussed at the plenary.

RAC agreed on no classification for acute toxicity via the oral route based on no mortality at 2 000 mg/kg bw in a rat gavage study. Reported cases of human intoxication were not regarded as relevant to the specific *Margosa extract* covered by the present CLH proposal.

Regarding STOT RE, one member noted that skin irritant properties should not be considered under this classification. Also the application of dermal STOT RE guidance values and Haber's rule to adjust them in the rabbit study was considered inappropriate in the absence of systemic effects. RAC agreed that the classification for STOT RE 2 (skin, dermal) is not warranted considering the low severity of the effects, which did not increase in the second week of exposure.

RAC concurred with the DS and agreed to not classify reproductive toxicity due to insufficient data.

The DS initially proposed no classification for environmental hazards. However, following public consultation, the DS changed their position to consider *Margosa ext.* as not rapidly degradable taking into account comments received and the conclusion on the PBT status of the substance as agreed in the BPC working group meeting in December 2016 (i.e. after the initial proposal has been submitted to ECHA). RAC supported the Rapporteur's proposal which is in line with

that of the DS after PC and classified *Margosa extract* as Aquatic Chronic 3; H412. One RAC member recommended that future CLH proposals for similar substances should provide all available relevant information (e.g. QSAR, analogue data, etc.). The Secretariat informed on the sector-specific guidelines for the environmental assessment of natural complex substances (NCS) developed by industry in close cooperation with ECHA[5], which could be consulted in combination with ECHA guidance for future discussions.

In conclusion, RAC agreed on the opinion to classify *Margosa extract* as Aquatic Chronic 3 - H412 by **consensus.**

The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

11) ipconazole (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that ipconazole is an active substance used in plant protection products as a fungicide. The substance has no existing entry in Annex VI of the CLP Regulation thus in accordance with Article 36(2) of CLP all hazard classes need to be assessed. The legal deadline for the adoption of an opinion is 15 June 2018.

The DS (UK) proposed classification as Repr. 2; H361d, Acute Tox. 4; H302, STOT RE 2; H373 (eyes, skin, liver, gastrointestinal tract), and Aquatic Chronic 1; H410, M=100 to the existing harmonised classifications.

RAC agreed not to classify for the following hazard classes via the fast-track procedure, with scrutiny but without plenary debate:

- Acute toxicity via dermal and inhalation routes of exposure
- Skin corrosion/irritation
- Serious eye damage/eye irritation
- Respiratory/skin sensitization
- Germ cell mutagenicity
- Carcinogenicity
- STOT SE.

As well as classifications for the following hazards:

- Acute Tox. 4; H302, ATE = 500 mg/kg
- Aquatic Chronic 1; H410, M=100.

The Committee supported the classification into category 2; H373 for specific target organ toxicity after repeated / prolonged exposure; the discussion focused on the effects to different target organs.

The effects in the eyes / the liver were observed in two species (dog, mouse) and the meeting discussed possible relations between liver enzyme changes and effects on eyes (opacities, cataracts, lenticular degeneration observed in the dog). The IND expert informed RAC that on the individual level no correlation between eye effects and cholesterol level changes was demonstrated. Some RAC members considered the effects in the liver not severe enough to warrant classification, but the majority of members supported including both the liver and the eyes as target organs.

[5] https://echa.europa.eu/et/support/substance-identification/sector-specific-support-for-substance-identification/essential-oils

RAC did not support inclusion of gastrointestinal tract as a target organ because the findings in the rat and the mouse were considered rather a consequence of the irritant property of ipconazole. In addition they were observed only in the high dose group and were reversible.

The Committee agreed to include the skin as target organ based on effects observed in the dog (reddening of skin at low, mid and high doses, swollen eyelids and evidence of pain at the high dose) which RAC considered as clear systemic effects and signs of serious functional changes.

RAC briefly discussed the effects in the adrenals but found them not sufficient to fulfil the criteria and did not include the adrenals as the target organ.

RAC agreed that no classification for fertility effects was warranted. In response to a RAC member's question about parental toxicity in the rat study, the IND expert clarified that some effects on body weight gain were observed (up to 10%) but no other adverse effects were seen after histopathological examination. In addition, IND expert specified the dosing (following feeding patterns) to confirm that the dosing was appropriate.

Developmental toxicity was assessed based on two developmental toxicity studies in rats and two developmental toxicity studies in rabbits (preliminary and main studies for both species). RAC Members agreed to classify ipconazole into category 1B for developmental toxicity based on a high incidence of external malformations (microphthalmia) observed, occurring in several litters, and observed in both species (rats, rabbits), supported by other malformations (tail, changes to aorta). The meeting concurred that microphthalmia was a specific effect, related to ipconazole treatment and not known to be induced by (marked) maternal toxicity. In addition, there were increases in foetal resorptions/deaths resulting in reduced live foetuses per litter in both rats and rabbits.

Regarding physical hazards, the potential explosivity of ipconazole was discussed after a comment from a RAC member. Based on a weight of evidence approach, noting that all of the measured explosive properties were negative and that it is chemically highly unlikely for ipconazole to be an explosive, RAC agreed not to classify ipconazole for physical hazards (explosives).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

12) ethofumesate (ISO) (±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate

The Chairman reported that ethofumesate (ISO) is herbicide (inhibitor of cell division).

The substance has a harmonised classification and labelling entry in Annex VI of the CLP Regulation (Aquatic Chronic 2; H411). The DS (AT) proposes to classify the substance as Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=1).

The Committee concurred with the DS's proposal.

During the discussion on aquatic acute toxicity, the Committee considered that ethofumesate (ISO) is of low acute toxicity to fish, aquatic invertebrates, algae, and *Lemna* with reliable LC_{50}/EC_{50} values > 1 mg/L. However, the available acute toxicity data on aquatic macrophytes show E_rC_{50} values < 1 mg/L. Indeed, the most sensitive species tested was *Myriophyllum spicatum* with an E_rC_{50} of 0.479 mg/L, based on mean measured concentrations.

During the discussion on aquatic chronic toxicity, the RAC considered that the substance is of moderate chronic toxicity to fish and aquatic invertebrates with NOECs of 0.156 mg/L and 0.25 mg/L, respectively, and of low toxicity to algae and *Lemna*, with NOECs > 1 mg/L. However,

aquatic macrophytes showed higher toxicity where the most sensitive species tested was *Myriophyllum spicatum* (14-day static condition test) with NOE_rC = 0.036 mg/L, based on mean measured concentrations.

The Committee concluded that ethofumesate (ISO) is considered not rapidly degradable and does not fulfil the criteria for bioaccumulation. The lowest acute toxicity value falls in the range of 0.1 < $L(E)C_{50}$ ≤ 1 mg/L and the lowest chronic toxicity value lies in the toxicity range of 0.01 < NOEC ≤ 0.1 mg/L.

The committee noted that the data driving the classification is derived from *Myriophyllum spicatum*, which is not currently a widely used species in aquatic toxicity testing. Furthermore, the test guideline used was adapted from OECD TG 221 by using the draft guideline, which would become OECD TG 239 (a 14-day guideline with sediment). In the test submitted, the *Myriophyllum* was rooted in sediment and run for 14 days, deriving both acute and chronic endpoints. The committee discussed the 14-day duration of the test, noting that the time period does not allow for multiple generations, a normal prerequisite for chronic toxicity testing with plants. As multiple generations could not be demonstrated, it was concluded that the endpoint was not equivalent with that from a standard algal test or with a plant such as *Lemna*. However, as the substance is a herbicide and had severe effects on growth of plant filaments, it was concluded that the data will be considered both acute and chronic in this case. Further consideration was given to the presence of sediment in the test system, with concern expressed that the presence of sediment added uncertainty to the interpretation of the results. This was especially the case in the absence of information on the constituents of the sediment, particularly with regard to the organic carbon (OC) content. The view was expressed that any future guidance on the use of studies with sediment could consider a method of standardising results with regards to the OC content. In this case, it was concluded that although the substance concentration in the sediment was not tested, the mean measured concentrations in the water phase (74 – 83% of nominal) demonstrated sufficient aqueous exposure and that if test material was lost to the sediment the results would be conservative. The committee agreed to use the *Myriophyllum* study for the classification of ethofumesate, although in general studies with sediment are not preferred due to potential problems with interpretation of results. RAC also impressed upon the secretariat that the preparation of guidance for the new OECD guidelines (OECD TG 238/239) would be especially helpful, particularly where sediment is included in the study design.

In conclusion, the Committee agreed to classify ethofumesate (ISO) as Aquatic Acute 1; H400 (M = 1) and Aquatic Chronic 1; H410 (M = 1) by consensus.

The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

13) L-(+)-lactic acid; (2S)-2-hydroxypropanoic acid

The Chairman reported that L-(+)-lactic acid is an active substance used in biocidal products as a disinfectant in human hygiene products. The substance has no existing entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 22 August 2018.

The DS (DE) proposed to classify the substance as Skin Irrit. 2; H315, Eye Dam. 1; H318 and STOT SE 3 (respiratory tract irritation); H335.

No classifications for the following hazard classes were agreed via the fast-track procedure:

- Physical hazards
- Environmental hazards

- Acute toxicity (all routes of exposure)
- Skin sensitisation
- Specific target organ toxicity – repeated exposure
- Germ cell mutagenicity
- Carcinogenicity
- Toxicity to reproduction.

In the absence of human data and of pathological examination at necropsy in the acute inhalation toxicity rat study RAC agreed that no classification for respiratory tract irritation was warranted.

The Committee agreed to classify L-(+)-lactic acid as corrosive to skin (Skin Corr. 1C) based on the evidence in rabbits (effects such as necrosis, formation of scar tissue and blanching), supported by positive results of an *in vitro* transcutaneous electrical resistance (TER) test with human skin. The available human patch test study was acknowledged to be not appropriate for assessing skin corrosion. Generic concentration limit was found appropriate and therefore no need for specific concentration limits.

After a short discussion and following an explanation by the Secretariat about the criteria for applicability of the supplemental hazard information EUH071 (corrosive to the respiratory tract), RAC agreed to assign the supplemental hazard information EUH071 to L-(+)-lactic acid.

The Committee supported classification of the substance as causing serious eye damage (Eye Dam. 1) based on severe corneal effects in an *in vitro* Chicken Enucleated Eye Test (CEET) using 88% L-(+)-lactic acid, supported by an ocular tolerance study in the rabbit.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

14) 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9-rich; [1] di-"isononyl" phthalate; [2] (DINP)

The Chairman welcomed the experts, each accompanying the Cefic, VinylPlus, ECETOC and EuPC stakeholder observers and reported that DINP is an industrial chemical primarily used as a plasticiser for synthetic PVC. The substance has no existing entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 28 September 2018.

The DS (DK) proposed to classify the substance for toxicity to reproduction (Repr. 1B; H360Df).

The Secretariat presented the meeting with a short summary of the open Rapporteurs' dialogue held on the proposal prior to the plenary discussion, on 1 February 2018 with the aim to provide an additional opportunity to the Dossier Submitter (DS) and to Stakeholders to inform the rapporteurs and the Committee on the case.

RAC discussed sexual function and fertility and agreed that the effects seen on reproductive organ weights and on sperm number and motility were not sufficient to justify classification as they were minor and did not demonstrate a pattern that would indicate that they were related to treatment. Furthermore, no effects on male and female reproductive performance were seen in rats at doses up to 1.5% DINP (1 087–1 186 mg/kg bw/d), nor were any adverse effects on fertility observed in the 13-week chronic toxicity study in marmosets. In addition, available human data (four studies assessed in the CLH report) showed no clear association between adult exposure to DINP and fertility parameters such as sperm parameters, hormone levels or time to

pregnancy. Taking all this into account, RAC agreed that no classification for fertility was justified.

In the discussion about developmental toxicity RAC recognised the occurrence of some dose-dependent skeletal variations, but did not consider these to fulfill the criteria for classification. In contrast to other phthalates DINP does not induce gross-structural malformations, such as hypospadias and cryptorchidism in rats, nor permanent decreases of anogenital distance (AGD) or permanent nipple retention. Neither was the decreased level of testosterone production in testes found sufficient for classification, also noting that no significant difference in plasma testosterone level was observed. No conclusion on the potential correlation between DINP exposure and possible effects on male reproductive organs or other endpoints in humans could be drawn from the epidemiological studies included in the CLH dossier. Taking all available data into account, RAC agreed not to classify DINP for developmental effects.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

15) (2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that mefentrifluconazole is a new active substance used in plant protection products as a fungicide. It has no existing entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 24 October 2018.

The DS (UK) proposed to classify mefetrifluconazole as Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with an M-factor of 1 for both.

The following hazard classes were agreed via the fast-track procedure:

- physico-chemical properties (except explosives, self-reactive substances and mixtures and oxidising solids) – no classification
- Acute Tox. (dermal and inhalation routes of exposure) – no classification
- Skin corrosion / irritation – no classification
- Serious eye damage / eye irritation – no classification
- Skin Sens. 1; H317
- Germ cell mutagenicity – no classification
- Carcinogenicity – no classification
- Aquatic Acute 1; H400, M=1
- Aquatic Chronic 1; H410, M=1.

Based on a weight of evidence approach, noting that all of the measured explosive properties were negative (behaviour to heat, shock and friction), RAC concluded that the substance is not explosive. The chemical structure of mefentrifluconazole is stable and the available calorimetric data show low reactivity. However, RAC was of the opinion that the self-reactive properties of mefentrifluconazole cannot be assessed due to lack of data as presented in the background document. The industry expert accompanying the regular stakeholder organisation could not clarify this endpoint during the discussion but provided a statement to the secretariat after the plenary. He noted that the available information was hidden in the background document and concluded that mefentrifluconazole is not considered self-reactive. RAC is however not in a

position to review this information and therefore, the RAC conclusion remains valid. Finally, RAC agreed not to classify mefentrifluconazole as an oxidising solid based on the weight of the overall evidence, also noting that mefentrifluconazole proved to be negative using a method that is repealed by the CLP Regulation[6].

In relation to acute oral toxicity, RAC discussed the three rabbit studies (dose range-finding studies in preparation for the main prenatal developmental toxicity study) with lethal effects to non-pregnant and pregnant rabbits at doses that are relevant for Acute Tox. 2; H300 classification (5 mg/kg < Category 2 ≤ 50 mg/kg). Some RAC members were of the view that the rabbit studies should not be considered in the overall evaluation because of the rabbit not being a preferred species for acute oral tests, in line with the CLP Regulation. The industry expert accompanying the regular stakeholder organisation clarified the time of death of the animals occurred after repeated dosing, thus the range-finding study would not be appropriate to use for acute toxicity classification. Other members preferred that the rabbit data be assessed in a weight of evidence assessment under the hazard class for acute toxicity, acknowledging the species particularities and the very specific sensitivity of the rabbit to mefentrifluconazole. The Committee agreed that the observed effects were not sufficient for the classification for acute oral toxicity, noting also that the effects in in rats were not severe and of reversible nature.

In relation to respiratory irritation in the context of STOT SE, the Committee assessed the (according to some members rather severe) sub-lethal effects and symptoms observed in the acute inhalation study. After a short discussion, RAC agreed that the data were not detailed enough (no histopathological information on the lung tissues) and that the symptoms could also be related to general toxicity. In addition, some deviations in the study protocol compared to the OECD test Guidelines (lower relative humidity and thus probably high dust concentration) were reported. One of the arguments used was that the respiratory symptoms were observed at too high a concentration to be relevant (5.3 mg/L mist/dust in this case). One member was concerned that RAC introduced a threshold/limit concentration that is not present in the CLP-criteria, and in order to obtain consistent classification decisions it is very important that it is clarified whether there is a limit concentration for STOT SE3 respiratory irritation. And if so, at what concentration. RAC concluded on no classification for respiratory irritation.

Regarding repeated dose toxicity, data from the rat, mouse and dog were available showing adverse effects in the liver, with the mouse being the most sensitive species. However, the effects (fatty changes in males at the middle dose and both males and females in the high dose) in the 18-month mouse study were considered not severe and inconsistent across studies, thus considered not sufficient for classification. RAC Members pointed out that also the findings of the rabbit range-finding study (discussed also in relation to acute oral toxicity) need to be taken into account (also as the mode of action was not known) in the weight of evidence. The industry expert raised the issue of the specific diet and digestion pattern of rabbits compared to rats and humans; some members were of the view that in this specific case the rabbit data would not be relevant to humans. Finally, RAC agreed that classification for STOT RE is not required.

RAC agreed on no classification for sexual function and fertility based on the 2-generation reproductive toxicity study in rats that showed effects that were not consistent or observed only with concurrent maternal toxicity and within the historical control data.

[6] Mefentrifluconazole was not previously classified under the Dangerous Substance Directive (DSD, 67/548/EEC) but was tested with a method compliant to this directive. Moreover, based on the chemical structure evaluation, the requirement for testing appears in fact debatable and the experience accumulated in practice does not suggest any oxidising property.

For developmental toxicity, data from rats and rabbits were evaluated. RAC concurred with the Dossier submitter that the overall evidence appeared to be variations and due to slight developmental delays and not malformations (some skeletal variations and dilated renal pelvis in the rat, fused sternebra (with unchanged cartilage) in the rabbit). In addition, these effects were within the range of historical control data and thus the classification was not warranted.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

16) MCPA-thioethyl

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that MCPA-thioethyl (ISO) is an active substance used in plant protection products as an herbicide and plant growth regulator. The substance has no existing entry in Annex VI of the CLP Regulation. Legal deadline for the adoption of an opinion is 2 May 2018.

The DS (PL) proposed to classify the substance for acute oral toxicity (Acute Tox. 4; H302) and for environmental hazards (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with an M-factor of 10 for both).

RAC discussed the proposal at its plenary meeting in December 2017 and agreed to classify MCPA-thioethyl for the following hazards:

- Acute Tox. 4; H302, oral ATE=450 mg/kg bw
- Aquatic Acute 1; H400, M=10
- Aquatic Chronic 1; H410, M=10.

In addition, no classification was agreed for the following hazards –

- physical hazards,
- acute toxicity (dermal and inhalation routes of exposure),
- skin corrosion / irritation,
- serious eye damage / eye irritation,
- germ cell mutagenicity,
- carcinogenicity and
- aspiration hazard.

In accordance with the RAC 43 conclusions on the dossier, the manufacturer provided further details for the repeated dose toxicity studies (three repeated dose toxicity studies not included in the original CLH proposal and the repeated toxicity study in dogs by Reuzel et al., 1980 which lacked details in the CLH proposal). These studies, the research developmental toxicity study in mice by Roll and Matthiaschk, 1983 which was made available at a late stage of the process and two abstracts of teratogenicity research studies Ujhazy, 2006 and Yasuda, 1972 were subject to a targeted public consultation (17/01 – 31/01/2018) prior to the RAC 44 plenary discussion.

As regards specific organ toxicity after repeated exposure, RAC agreed to classify the substance into category 2 for effects on the liver seen in the dog studies (at doses of 12-48 mg/kg bw/d; changes in liver enzymes (ALT increase and ALP decrease), indication of hepatic cell damage confirmed by findings of necrosis and inflammatory changes in the hepatic tissue) noting that the dog might be more susceptible to toxic effects compare to the rat and the human.

The Committee agreed not to classify MCPA-thioethyl for effects on fertility based on the observations in rats and dogs where no effects on fertility and reproductive tissues were observed in the rat 1- and 2 generation studies (noting though that the top dose levels may not

have been high enough); the effects in the dog study were reversible and no effects on sperm nor testes were reported in mice or rabbits.

As regards developmental toxicity, several studies were available in mice, rats and rabbits. The evidence in the rat studies (reduced foetal weight, skeletal ossification and severe malformations of the head in two foetuses at 120 mg/kg bw/d and increased resorptions; cleft palate, renal and cardiac malformations at ≥60 mg/kg bw/d and in the mouse study (severe teratogenicity (post implantation loss, cleft palate) at ≥200 mg/kg bw/d; reduced foetal weight at ≥100 mg/kg bw/d were discussed and assessed in the weight of evidence approach. The reliability of some studies (namely the Yasuda et al., 1972 rat study and the Roll and Matthiaschk, 1983 mice study) was questioned by some RAC members due to the excessive dosing exceeding MTD (maximum tolerated dose) and an overall low quality of the reporting (i.a. missing information on the test material, impurities) related to these studies. Giving lower weight to these two studies the overall evidence was found not sufficient for the classification. In particular, the Roll and Matthiaschk study showed seldom seen, extreme reproductive toxicity and was inconsistent with the other studies. It was also noted that previous evaluations in the EU (PPP, CLH) had not identified a reprotoxic concern based on these studies.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

9. Restrictions

9.2 Restriction Annex XV dossiers

a) Opinion development

1) Lead in shot

The Chairman welcomed the Dossier Submitter's representatives from ECHA, an industry expert (FACE) accompanying a regular stakeholder observer and a representative from the UNEP-Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA), accompanied by an expert. He reminded the participants that this restriction proposal had been submitted by ECHA in April 2017 and had been considered in conformity by RAC in its May/June plenary. The dossier proposes a restriction on the use of lead shot in wetlands. The harmonisation of the conditions of use of lead in shot with respect to wetlands is a priority at EU level as national legislation has already been enacted by some Member States (or regions in some Member States). The phasing out of lead gunshot in wetlands is also required under the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA), under the auspices of the UN Environment Programme (UNEP), to which the EU and many Member States are Parties. The Chairman reminded the Committee that the public consultation on this restriction proposal ended on 21 December 2017 with 278[7] comments received. The third draft opinion was made available to the Committee on 7 February 2018 and comments by two RAC members were received during the subsequent commenting round.

The Rapporteurs highlighted the comments received during the public consultation and the advantages and disadvantages of establishing, so called, "buffer zones" surrounding wetlands, which were not explicitly included in the Dossier Submitter's proposal. The Chairman invited the Committee to discuss the third draft opinion with the aim to adopt the RAC opinion.

[7] Comments containing offensive language received during the public consultation are considered to be inappropriate and they are discounted from the total number of the received comments.

The Rapporteurs highlighted the following items as the key issues raised during the public consultation: the scope of the restriction, including the use of the Ramsar Convention definition of a wetland and the wording of the entry (specifically the word 'use', which under the REACH Regulation includes 'any keeping', i.e. possession), the transitional period for compliance, the suitability of alternatives and the proportionality of the restriction proposal.

Several public consultation comments from hunting organisations questioned whether the inclusion of peatlands in the scope of the restriction was appropriate and proportionate. However, UNEP/AEWA and other stakeholders provided supporting evidence in the public consultation that the inclusion of peatlands would be justified based on the identified risks. The Rapporteurs confirmed their support for the use of the Ramsar Convention definition of a wetland (including peatland) to establish the scope of the restriction.

Regarding 'possession' of lead gunshot, the Dossier Submitter noted that compliance problems have been widely reported in Member States with partial bans on the use of lead gunshot. The proposal to explicitly prohibit the possession of lead gunshot in wetlands recognises that 'use' under REACH extends to 'possession' and that, as such, possession-based enforcement could be applied by Member States. The Rapporteurs acknowledged the explanation provided by the Dossier Submitter and supported the inclusion of possession of lead gunshot within the scope of the restriction. Assuming that 'use' includes possession, there are practical reasons to consider that 'possession' should be interpreted as 'possession while hunting/sport shooting'.

The Rapporteurs noted that many public consultation comments were received in relation to the transitional period, either requesting a longer or shorter transition period than the three years proposed by the Dossier Submitter. The Rapporteurs explained that considering that current restrictions are already in place in 24 EU Member States, the fact that each year of continued use of lead shot results in up to 7 500 tonnes of lead being released to wetlands and the lethal poisoning of approximately one million waterbirds, the Rapporteurs strongly supported that the restriction should enter into force more quickly than proposed by the Dossier Submitter.

The industry expert (FACE) accompanying a regular stakeholder observer discussed a number of points submitted during the public consultation by some hunters' organisations. Based on the available evidence, RAC members supported the view of the RAC rapporteurs. Regarding "buffer zones" around wetlands, RAC considered three alternatives: no buffer zone as proposed by the Dossier Submitter (to avoid an expansion of the scope into terrestrial areas), a small zone of 20-30 m and a wider zone of 200-300 m. The intent is to prevent shooting over or into wetlands in all cases. While many members were in favour of a wider zone, others considered that the scientific evidence did not support this clearly. Additional feasibility for enforcement from the introduction of such a buffer zone was also seen as uncertain. The Chairman summed up that there was insufficient evidence to support one buffer zone option over the others and suggested that the Committee follow the Dossier Submitter proposal, which after some discussion was agreed. It was also agreed that the analysis in the opinion should clearly reflect the aspects of risk and enforcement for all three options. The wording of the proposal allows Member States to take more stringent measures (which could include buffer zones) if they wish.

It was also agreed that the Rapporteurs would add further clarifications in the final opinion on the difference between the Ramsar Convention definition of a wetland and Ramsar 'sites', to avoid any misunderstanding on the scope of the proposal.

The Committee adopted its opinion on the restriction proposal on lead in shot over wetlands (with modifications agreed at RAC-44) by consensus. The Rapporteurs were requested, together with the Secretariat, to make the agreed amendments to the adopted RAC opinion and to ensure that the supporting documentation (Background Document and Responses to comments from the public consultation) is in line with the adopted RAC opinion. The Chairman thanked the

Rapporteurs for their efficient and thorough handling of this restriction proposal, the Committee Members and the stakeholders for their contributions.

2) Substances used in tattoo inks and permanent make-up

The Chairman welcomed the RAC Rapporteurs, SEAC Rapporteurs and representatives of the Dossier Submitter (from Norway and ECHA) and Dossier Submitter experts from Germany. The restriction proposal was submitted by ECHA together with Denmark, Italy and Norway on 6 October 2017. In addition, Germany contributed significantly to the proposal. The proposal aims to restrict the intentional use of certain substances in tattoo inks or to impose concentration limits for selected substances. These substances include those with harmonised classifications as carcinogenic, mutagenic, reprotoxic, skin sensitising/corrosive/irritant, eye damaging/irritant as well as other substances prohibited in cosmetic products (under the Cosmetic Products Regulation, (EC) 1223/2009) and selected impurities. A number of colourants, which do not currently have alternatives or where information is insufficient to demonstrate risk, are exempted. Two restriction options (RO1 and RO2) with the same scope are proposed. They differ in terms of the proposed concentration limits and how the links with the Cosmetic Products Regulation annexes are managed.

The Rapporteurs then presented the first draft opinion. They outlined the scope of the restriction, and as a reply to member's comment, explained that the professional use is not in the scope of the restriction. As the profession of tattooist is not well-defined in the EU, obtaining data for risk assessment is rather difficult. However, the Rapporteurs pointed out that the proposed restriction is expected to also lower health risks for tattooists. In response to another question by a member the Rapporteurs confirmed that preservatives are included in the scope, if they are classified as CMRs, skin sensitisers, or skin/eye irritants/corrosives.

RAC agreed with Rapporteurs' conclusions that chemicals in tattoo inks can pose a health risk for the general population, although incidence and prevalence of tattoo-related adverse health effects is difficult to assess at the present moment. After some discussions on local effects, the Chairman concluded that RAC considered that there is more evidence for the adversity of local (skin) effects (need to consider sensitizers and irritants further) than for other toxic effects e.g. CMR but this does not exclude any of the substances from scope. Furthermore, RAC discussed the inhalation route and agreed that substances classified only via inhalation route are exempted from the scope and further justification would be added to the opinion. The RAC opinion would not consider worker issues in general as these are not in the scope of the proposed restriction.

RAC also supported the rapporteurs' assessment, while taking into account the uncertainties, on the proposed exposure scenario. In addition, RAC had general support for including substances restricted by CPR (Cosmetics Products Regulation) without traceable opinions of the Scientific Committee on Consumer Safety (SCCS).

More specifically, RAC supported the qualitative assessment of all substances with harmonised classification as carcinogenic (C) and mutagenic (M) Category 1A, 1B and 2 (except those classified only for inhalation route) to be restricted in tattoo inks. RAC in principal supported the approach taken for a (simple) quantitative assessment of all substances with harmonised classification as category repro 1A/B and 2 to be restricted in tattoo inks, but questioned using the lowest DNEL for all substances given the wide range in values.

The Rapporteurs were requested to prepare the second draft opinion, taking into account RAC-44 discussions, by beginning of May 2018. Finally, the Chairman noted that due to complexity

of this restriction proposal, the Committee might need more time to address all aspects than specified in the process timelines.

3) C9-C14 Perfluoro Carboxylic Acids, their salts and related substances (further, C9-C14 PFCA)

The Chairman informed the participants that the restriction dossier had been submitted by Germany and Sweden in October 2017 and proposes to restrict the use, placing on the market and import of C9-C14 PFCAs, on their own or in a mixture or in an article or parts therein in a concentration equal to or above 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related substances. Thus, articles and mixtures manufactured in Europe can comply with the proposed threshold. C9-C14 PFCAs are mainly unintended by-products occurring during the manufacturing of per- and polyfluorinated substances containing a carbon chain of less than nine carbon atoms, such as perfluorooctanoic acid (PFOA, C8-PFCA) based substances and perfluorohexanoic acid (C6-PFCA) based substances.

The Rapporteurs presented the first draft opinion. With regard to the scope of the restriction, they explained that at the first Rapporteurs' dialogue, it was agreed to prepare a revised entry in order to clarify a number of its components and to prepare an explanatory text for each component. The draft entry was included in the first draft opinion for transparency reasons, but is still under discussion with the Dossier Submitter. The Rapporteurs proposed and RAC agreed regarding the scope that the PBT/vPvB properties of C9-C14 PFCAs and their salts are sufficient to justify the restriction and that PFCA-related substances, which degrade to C9-C14 PFCAs should also be included. C9-C14 PFCAs do not undergo any further abiotic or biotic degradation under environmentally relevant conditions and may cause severe and irreversible adverse effects on the environment and to human health if their releases are not minimised. According to REACH, the risk cannot be adequately controlled for PBT/vPvB substances and no safe concentration, thus no threshold (PNECs/DNELs) can be determined for PBT/vPvB substances.

RAC took note of the human health hazards of some of these substances, but agreed that assessment of these endpoints is not necessary to demonstrate the risk, which for human health and environment can be done only qualitatively. Furthermore, RAC concluded that C9-C14 PFCA-related substances are degraded to C9-C14 PFCAs in the environment - they need to be considered as PBT-substances. The Secretariat added that in the case of this particular restriction, there are no intentional uses and therefore no negative impact for industry is expected.

RAC also agreed with the Rapporteurs' conclusions on exposure and emissions - that properties of the PBT/vPvB substances lead to an increased uncertainty in the estimation of exposure to human health and the environment and the focus is therefore on the assessment of the releases. Even if uncertain, the release estimates provide a sufficient basis to conclude that current and potential future uses of C9-C14 PFCAs and related substances lead to releases. The Rapporteurs emphasised that there are indications that C9-C14 PFCAs, their salts and related substances could be present also in imported goods and articles. Although releases in the EU are expected to decrease by 2020 due to the PFOA restriction, as impurities in C6 alternatives and from the manufacturing of those C8 substances that are derogated in the PFOA restriction, they remain relevant.

Finally, RAC supported the view of the Rapporteurs on the characterisation of risks – that for PBT and vPvB substances quantitative risk assessment is not possible and the aim is therefore to demonstrate that releases have been minimised. Data available indicates current and future emissions and exposure to the environment and humans.

The Rapporteurs were asked to prepare the second draft opinion, taking into account the RAC-44 discussion, by beginning of May 2018.

10. Authorisation

10.1 General authorisations issues

a) Update on incoming/future applications

The Secretariat informed the Committee that no new applications for authorisation or review reports had been submitted during the February 2018 submission window. The Secretariat estimated around 10 applications for authorisation and review reports might be submitted to ECHA during the second half of 2018.

b) Information about the rapporteurs/RAC-members workshop on new AfA opinion template

At the preparatory RAC rapporteurs/members workshop held on 27 February, the Secretariat presented the new Authorisation opinion template. Participants expressed general support for the proposed changes and agreed that from the administrative point of view the new structure of chapters is appropriate. They found the idea of introducing separate short summaries of both the authorisation case and the justification very useful. The intention is to remove the bulk of the description and analysis of the operations conditions, risk management measures and exposure data to an annex. The authorisation summary will be prepared by the ECHA Secretariat while the Justification summary will be prepared in collaboration between rapporteurs and the ECHA Secretariat but is primarily the responsibility of the rapporteurs.

The new template should substantially reduce the length of the opinion and provide text that is more suitable for writing the conditions of the decision. One member noted that it should also limit unnecessary repetitions between the RAC and SEAC sections, e.g. new section 1. "Short description of use".

The participants proposed that sub-headings for "justification summary" and "the full justification Annex" should be similar to ease cross-references and they asked to add an index/table of contents to improve the readability.

In the second part of the discussion the secretariat raised the key concluding phrase used from the start of the process until now: "appropriateness and effectiveness of OCs/RMMs in limiting the risks" for informal discussion. Two options suggested were the complete removal of "in limiting the risk" from the opinions or replacement with the phrase "in limiting the exposures". Then participants presented their own understanding of definitions of the "appropriateness" and the "effectiveness" of the OCs/RMMs, concluding that these terms needed better definition going forward.

The summary of the workshop was presented at the RAC 44 plenary.

10.2 Authorisation applications

a) Discussion on key issues

The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding the three new applications for authorisation received during the November 2017 submission window.

1. **DBP_AVX**

This is a downstream application for authorisation for the industrial use in the manufacture of ceramic sheets for the production of multi-layer ceramic capacitors. It has a narrow scope and is well defined, covering 1 use (1 ECS, 11 WCS) by 1 company, at 1 site in the UK. The information about total number of workers exposed is unclear as yet. A quantity of 1-10 tonnes per year is used and a 7 year review period has been requested.
Modelled exposure data was provided. As presented by applicant, the RCRs are < 1 for all WCS and the combined-exposure RCR was also < 1, while the RCR for humans via environment was < 0.01.
The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding this new application. They outlined the key issues identified by the Rapporteur and asked the Committee for comments and further suggestions. RAC will request further clarifications from the applicant as appropriate.

2. Diglyme_Omnichem

This is the downstream application for authorisation on the single use of diglyme as a solvent for the synthesis of the anti-HIV active pharmaceutical ingredient dapivirine. It involves a pilot and commercial scale installation (the latter used only once so far, but is foreseen to be used if authorisation is granted), located on one site, involving 5 workers and the use of 1-10 tonnes of diglyme per year.
Personal and static measurements performed for inhalation exposure, covering most WCSs were supplemented by modelling (ART, TRA). Dermal exposure was based on RISKOFDERM with TRA used as supportive information. The applicant's RCR for combined WCSs performed during one shift were up to 0.35 for the commercial plant and up to 0.40 for the pilot plant, while the RCRs for man via the environment were 10^{-5} (local scale), 10^{-8} (regional scale). The applicant had requested a 7 year review period.
In the presentation of the case, the Secretariat outlined the key issues identified by the Rapporteur and asked the Committee for comments and further suggestions.
RAC will request further clarifications from the applicant as appropriate.

3. SD_Olwerke

Two Ammonia Absorption Deep Cooling (AADC) systems are operated, one by each of the applicants in their refineries in Hamburg and Salzbergen (Germany) respectively. This is a downstream application for authorisation on the use of sodium dichromate as a corrosion inhibitor in the cooling systems, applied for the dewaxing and deoiling process steps of petroleum raffinate. Sodium dichromate is used in the working fluid (ammonia water mixture) of the AADC systems as additive to inhibit corrosion of the carbon steel the systems are made of. Up to 0.01 tonne is used across two sites. The applicant requested a 20-year long review period.

For each of the activities the exposure levels are calculated on the basis of modelling with ART 1.5 for inhalation exposure (combined exposure of the order of 10^{-3} ng/m^3 leading to an excess risk of 10^{-9}) and MEASE for dermal exposure.

The solution containing sodium dichromate is ordered from the supplier only when required and is not stored on the site, but instead is introduced into the cooling systems instantly upon arrival. The cooling circuit itself is a closed system, allowing only minimal amounts of the cooling medium to be released during the main steps of sampling and concentration adjustment.

The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding this new application. RAC will request further clarifications from the applicant on the issues identified and discussed by the Rapporteurs and the Secretariat.

b) Agreement on Draft Opinions

1. CT_Hapoc (2 uses)

The Chairman informed the Committee that on 8 February 2018 ECHA received a letter from the applicant (document RAC/44/2018/04), informing the agency of their decision to 'subsume' Uses 2 to 4 of their application for authorisation under one single use. Furthermore, they had changed the use title by removing the reference to a given risk level to read: "*Use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without current flow*". The Chairman noted that the draft opinion on Use 2 had been agreed at the previous meeting, as in practise, there was only one (worst case) dataset which it was possible to evaluate by RAC (Use 2). Furthermore, there is now no longer any need to refer to the applicant's view on the acceptability of any particular risk level (for a genotoxic carcinogen without threshold) as originally proposed by them. As requested by RAC, the rapporteurs, together with the Secretariat modified the draft opinion on Use 2 of CT_Hapoc subsuming the Uses 2, 3, and 4, and consulted the Committee prior to the RAC-44 plenary meeting. In line with the altered situation, the Rapporteurs and the Secretariat made appropriate changes to the draft opinion on Use 2. The RAC Chairman also informed the Committee that the applicant suggested for practical reasons to change the language of communication between ECHA, its scientific committees and the applicant to English.

The RAC rapporteurs then presented the draft opinion on Use 1 (formulation). RAC members discussed input parameters used by the applicant for modelling of the worker exposure, including the efficiency of local exhaust ventilation claimed by the applicant, and the additional risk management measures and operational conditions in the draft opinion proposed by the rapporteurs. A stakeholder observer organisation questioned the use of modelled data in the draft opinion and the level of uncertainty corresponding to it. The Secretariat explained that the Chemical Safety Report submitted as part of the application package contains a limited number of worker exposure measurements and they correlate with the modelled data.

RAC was of the opinion that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. The Committee decided to recommend additional conditions and monitoring arrangements for the authorisation and the review report as explained The Committee agreed on the draft opinion on Use 1 as proposed by the Rapporteurs by consensus. in the draft opinion. RAC also agreed to give no advice to SEAC on the length of the review period.

2. CT_Hapoc_2 (1 use)

This is an upstream application for authorisation for the "*use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of plastic, with or without current flow*". This upstream application in fact covers a single downstream user operating two fully automated, open 'plating on plastic' lines at one site. The number of workers exposed and the tonnage of Cr(VI) used are well documented. .

The RAC rapporteurs presented the draft opinion on the use of chromium trioxide. The Committee members discussed in detail the operating conditions and risk management measures limiting the exposure to chromium trioxide in this specific workplace as well as the results of biomonitoring included in the application for authorisation. The observer from the

European Commission requested more clarity on the qualitative descriptors of the worker exposure used in the text of the draft opinion.

RAC was of the opinion that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. The Committee decided to recommend additional conditions and monitoring arrangements for the authorisation as explained in the draft opinion. RAC also agreed to give no advice to SEAC on the length of the review period. The Committee agreed on the draft opinion by consensus.

3. CT_Hapoc_3 (1 use)

This is an upstream application for authorisation for the single "*use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of brass, bronze, copper and other copper alloys for medical engineering, aviation and automation products*". The application, in fact, concerns one open manual plating line and the applicant listed risk management measures typically used in functional chromium plating. These include coverage of baths, general ventilation and local exhaust ventilation, the use of mist suppressants and restricted access to specific areas.

The Committee discussed the operational conditions and risk management measures limiting the exposure to chromium trioxide in this specific workplace. RAC members also discussed the available biomonitoring data, which generally support the exposure data generated with the ART Modelling tool.

After the plenary discussion the Committee agreed on the draft opinion as proposed by the Rapporteurs by consensus. RAC was of the opinion that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. The Committee decided to recommend additional conditions and monitoring arrangements for the authorisation as explained in the draft opinion. RAC also agreed to give no advice to SEAC on the length of the review period.

4. SC_Wesco (1 use)
5. DtC_Wesco (1 use)
6. PCO_Aviall (2 uses)

The Rapporteurs presented the four draft opinions on the three applications for authorisation submitted by upstream users.

SC_Wesco is an upstream single use application on the use of strontium chromate in primers applied by aerospace and defence companies and their associated supply chains. The scope of the application is relatively broad. The number of sites relevant for the application is > 100. Number of workers exposed > 15 000. The applicants requested a review period of 12 years. The substance is the main component in primers. These are one layer out of several layers of coating applied (i.e. spraying and brushing) to the surface of an aeronautic vehicle or component. The level of containment for tasks and processes is generally low.

DtC_Wesco is an upstream application on the use of dichromium tris(chromate) for chemical conversion coating applications by aerospace and defence companies and their associated supply chains. The scope of the application is relatively broad. The number of sites relevant for the application is > 100. Number of workers exposed > 10 000. The applicant requested a review period of 12 years. The substance is the main component in chemical conversion coatings used

to provide corrosion resistance to the surface of an aeronautic vehicle or component. The level of containment of the process/tasks is generally low.

PCO_Aviall is an upstream application on the following two uses of pentazinc chromate octahydroxide: Use 1: Formulation of mixtures, Use 2: Use of pentazinc chromate octahydroxide in wash primer, fuel tank primer and aluminized primer for the purpose of corrosion protection in aeronautic applications. The scope of the application is relatively broad. The number of sites relevant for the application is < 5 for Use 1 and < 100 for Use 2. Number of workers exposed < 50 for Use 1 and < 1 000 for Use 2. The applicants requested a review period of 12 years. The substance is the main component in primers. Primers constitute one layer out of several layers of coating applied (i.e. spraying and brushing) to the surface of an aeronautic vehicle or component. For both uses, the level of containment is low.

RAC members and the observer from the European Commission discussed specific issues, such as: exposure values of measured data versus modelled data, potential for exposure in spraying applications, qualitative descriptors of the worker exposure used in the text of the draft opinions, use of local exhaust ventilation as an exposure control measure for workers during the waste management phase; as well as, more generally, conditions in the draft opinions regarding environmental emissions.
RAC agreed by consensus on the draft opinions as proposed by the Rapporteurs. In particular, RAC was of the opinion that the risk management measures and operational conditions described in the applications are not appropriate and effective in limiting the risk to workers and the general population. RAC decided to recommend extensive additional conditions and monitoring arrangements for the authorisations and the review reports as explained in the draft opinions. In addition, RAC agreed to give no advice to SEAC on the length of the review period on the use of dichromium tris(chromate) and the Use 1 of penatzinc chromate octahydroxide in formulation of mixtures, and RAC recommended to SEAC to consider a review period of no longer than seven years on the use of strontium chromate and the Use 2 of pentazinc chromate octahydroxide.

7. PCO_IP (2 uses) – for discussion, not for agreement

This is a relatively broad scope application for the two uses of pentazinc chromate octahydroxide in formulation of mixtures (Use 1) and in stoved epoxy primer for corrosion protection of aircraft engine components in aerospace and aero-derivative applications (Use 2).
The annual volume used is < 100 kg/year for each of the 2 uses. It is used in < 10 sites (Use 1) and < 100 sites (Use 2). The applicant requested a review period of 12 years for each use.

The RAC rapporteurs updated the Committee Members about the opinion development progress. They noted that the exposure assessment done by the applicant is based on modelling. The rapporteurs also informed that some worker contributing scenarios, such as paint spraying and machining, have high exposure potential and reliance on respiratory protective equipment. The RAC rapporteurs also commented on the lack of information regarding the number and characteristics of companies which provided data on the exposure scenarios which makes it difficult to assess the representativeness of said data. They also noted the limited description of tasks, of risk management measures/operational conditions and how exposure may occur. The applicant indicated in the CSR that the exposure model provides rather conservative estimates.

For man via the environment, exposure emissions to the air are modelled by EUSES. However, man via the environment exposure emissions to the wastewater has not been assessed by the applicant, as they were assumed as negligible.

The trialogue meeting will take place later in March 2018. The RAC Rapporteurs will consider the applicants' responses received during and after the trialogue for drafting the opinions on the

application for authorisation, which will be tabled for discussion and agreement at the next Committee plenary meeting in June 2018.

c) Adoption of final opinions

No final opinions on the applications for authorisation had been discussed at this plenary meeting.

10.3 Review reports

a) Discussion on key issues

No key issues in the review reports had been discussed at this plenary meeting.

b) Agreement on draft opinions

1. **RR1_DEHP_VINYLOOP (2 uses)**
2. **RR1_DEHP_PP (2 uses)**

These are the first two review reports received by ECHA. The review reports were submitted separately by two of the three authorisation holders. Both companies are Italian waste recycling companies that process waste into flexible PVC recyclate.

Use 1 of the review report covers formulation of recycled soft PVC containing DEHP in compounds and dry-blends. The broad scope of Use 2 in the initial application is in both review reports reduced to three article groups. The authorisation holders state that the three article groups are not in the scope of ECHA's restriction proposal on four phthalates and the RoHS restriction. Use 2 covers industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce the following PVC articles: (1) articles used outside of the interior space in applications in the field of construction, civil engineering, garden features such as ponds and roofing, agriculture (including horticulture) and industrials workplaces without potential for mouthing or prolonged contact with human skin or any contact with mucous membranes; (2) articles used in interior space in industrial and agricultural workplaces; or (3) footwear used in professional, industrial and/or agricultural workplaces.

The maximum concentration of DEHP in PVC recyclate decreased from < 20% in the initial application for authorisation to < 5%. The annual volume of 1 000 – 4 000 tonnes in the initial application is reduced to 50 – 500 tonnes (Vinyloop) and 10 – 100 tonnes (Plastic Planet). The review reports suggest that the use of the DEHP-containing recyclate may take place at ≥ 8 sites and about 200 workers are exposed. Vinyloop Ferrara SpA requested a 7-year review period, whereas Plastic Planet srl requested 12 years.

The RAC rapporteurs gave an update on the status of the opinion development and presented their initial views on the risk assessment. The scope of the initial application was broad whereas the scope of the review reports has been reduced to three article groups. The rapporteurs are of the view that the exposure scenarios in the review reports are considered more specific than in the initial application. The exposure assessment for workers in the review reports was viewed to have improved over the assessment in the initial application: downstream user air monitoring and biomonitoring data specific to the supply chain with supportive modelling are provided.

In the discussion the RAC rapporteurs clarified several technical details of the exposure assessment. Following a question for clarification regarding the concentration of DEHP in

recyclate, the Secretariat explained that the authorisation holders measure content of DEHP incoming material and guaranteed that it is below 5%.

The rapporteurs informed the Committee that draft opinions on the review reports RR1_DEHP_VINYLOOP and RR1_DEHP_PP will be discussed and agreed at the next RAC plenary meeting in June 2018.

9 March 2018

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 44 **27 February – 2 March 2018**
6 - 9 March 2018
(Adopted at the meeting)

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/44/2018**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-43 minutes.
4. Appointment of (co-)rapporteurs	
a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests **SECR** presented document **RAC/44/2018/01.**	
5. Report from other ECHA bodies and activities	
a) Report on RAC 44 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/44/2018/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes	
c) General RAC procedures **SECR** presented document **RAC/44/2018/03.** **RAC** agreed on the proposal for the required competences, with the addition of other competences, and agreed on the selection procedure for co-opting additional members.	**SECR** to follow the selection procedure for appointment of co-opted members to RAC.

6. Requests under Article 77 (3)(c)	
6.1 General occupational exposure issues	
a) Feedback from the preparatory workshop on OEL	
RAC noted the information presented by the Secretariat.	
6.2 Dossiers occupational exposure - opinion development	
a) Nickel and its compounds The rapporteurs presented the final draft RAC-opinion. RAC discussed the final draft opinion. RAC adopted the opinion by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to the Commission. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and S-CIRCABC IG.
b) Benzene The Rapporteurs presented the final draft RAC-opinion. RAC discussed the final draft opinion. RAC adopted the opinion by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to the Commission. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and S-CIRCABC IG.
c) Acrylonitrile The rapporteurs presented the final draft RAC-opinion. RAC discussed the final draft opinion. RAC adopted the opinion proposal by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to the Commission.

	SECR to publish the adopted opinion and its supporting documentation on the ECHA website and S-CIRCABC IG.
7. Requests under Article 95 (3)	
-	
8. Harmonised classification and labelling (CLH)	
8.1 General CLH issues	
8.2 CLH dossiers	

A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate

Please mention any ATE values for acute toxicity, together with the applicable route of exposure, where these were agreed by RAC through fast-tracking.

B. Substances with hazard classes for agreement in plenary session

Please mention any ATE values for acute toxicity, together with the applicable route of exposure, where these were agreed by RAC, including those agreed through fast-tracking.

1. octamethylcyclotetrasiloxilane
2. branched hexatriacontane
3. 2-methoxyethyl acrylate
4. diisooctyl phthalate
5. imiprothrin (ISO)
6. silicon carbide (fibres fulfilling the WHO definition: diameter <3 µm, length > 5 µm and aspect ratio ≥ 3:1)
7. Granulated copper
8. nitric acid…%
9. pymetrozine (ISO)
10. Margosa, ext. [cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide]
11. ipconazole (ISO)
12. ethofumesate (ISO) (±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate
13. L-(+)-lactic acid; (2S)-2-hydroxypropanoic acid
14. 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9-rich; [1] di-"isononyl" phthalate; [2] (DINP)
15. (2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole
16. MCPA-thioethyl

1. Octamethylcyclotetrasiloxilane; [D4]	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Chronic 1; H410, M=10]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
2. branched hexatriacontane	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [no classification]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
3. 2-methoxyethyl acrylate	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Flam. Liq. 3; H226, Acute Tox. 4; H302, Oral ATE = 404 mg/kg bw, Acute Tox. 3; H331, Inhalation ATE = 2.7 mg/l, Skin Corr. 1C; H314, Eye Dam. 1; H318; Skin Sens. 1; H317, Muta 2; H341, Repr. 1B; H360FD, EUH071 (corrosive to the respiratory tract]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
4. diisooctyl phthalate	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360FD]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5. imiprothrin (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

[Acute Tox. 4; H302 (oral ATE=550 mg/kg bw), Acute Tox. 4; H332 (inhalation ATE=1.4 mg/L), STOT SE 2 (nervous system, oral, inhalation); H371, Carc. 2; H351, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10]	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
6. silicon carbide (fibres fulfilling the WHO definition: diameter <3 µm, length > 5 µm and aspect ratio ≥ 3:1)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [silicon carbide fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) Carc. 1B; H350i]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
7. Granulated copper	
RAC agreed by consensus to not classify granulated copper for human health. RAC discussed uncertainties related to data interpretation and normalisation with regard to the proposed environmental classification. The case is scheduled for adoption at RAC 45 (Table 2 below).	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and additional clarification provided by the DS and to provide it to SECR. **SECR** to launch second round of RAC consultations focusing on environmental classification. **Rapporteurs** to revise the opinion in accordance with the RAC comments. **SECR** will table the case for adoption at RAC 45.
8. nitric acid …%	
RAC agreed to assign a supplemental hazard information EUH071 (corrosive to respiratory tract). RAC discussed choice of ATE for Acute Tox. Based on measured data as a preference to the default ATE value given in the CLP Regulation. The case is scheduled for adoption at RAC 45 (Table 2 below).	**SECR** will formally ask the German Competent Authorities for further clarification about the acute inhalation toxicity study performed by IND (to provide quantitative animal data on the acute inhalation hazard of nitric acid, at the azeotropic point (approximately 70 %). **Rapporteurs** will revise the opinion based on the received information as necessary and provide it to SECR. **SECR** will table the case for adoption at RAC 45.
9. pymetrozine (ISO)	

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Repr. 2; H361fd, Aquatic Chronic 1; H410, M=1]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
10. Margosa, ext. [cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide]	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Chronic 3; H412]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
11. ipconazole (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360D; Acute Tox. 4; H302 (oral ATE=500 mg/kg); STOT RE 2; H373 (eyes, liver, skin); Aquatic Chronic 1; H410, M=100]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
12. ethofumesate (ISO) (±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Acute 1; H400, M=1, Aquatic Chronic 1; H410, M=1]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
13. L-(+)-lactic acid; (2S)-2-hydroxypropanoic acid	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

[Eye Dam. 1; H318, Skin Corr. 1C; H314, EUH071: 'corrosive to the respiratory tract']	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
14. 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9-rich; [1] di-"isononyl" phthalate; [2] (DINP)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [no classification]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
15. (2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1; H317, Aquatic Acute 1; H400, Aquatic Chronic 1; H410, M=1 for both]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
16. MCPA-thioethyl	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [STOT RE 2; H373 (liver)] ***Agreed at RAC 43***: Acute Tox. 4; H302, oral ATE=450 mg/kg bw, Aquatic Acute 1; H400, Aquatic Chronic 1; H410, M=10 for both]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
9. Restrictions	
9.1 Restriction Annex XV dossiers	
a) Opinion development	
1) Lead in shot Rapporteurs presented and RAC discussed the third draft opinion. RAC adopted the opinion on this	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation

restriction proposal (with modifications agreed at RAC-44) by consensus.	(BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and S-CIRCABC IG.
2) Substances used in tattoo inks and permanent make-up The Rapporteurs presented and RAC discussed the first draft opinion. RAC agreed that chemicals in tattoo inks pose a health risk for human population, although incidence and prevalence of tattoo-related adverse health effects is difficult to assess at the present moment. RAC considered that there is more evidence for the adversity of local (skin) effects (need to consider irritants further) than for other toxic effects e.g. CMR but is not excluding any of the substances from scope. RAC agreed that substances classified only via inhalation route are exempted from the scope and further justification would be added to the opinion. The opinion would not consider worker issues in general as these are not in the scope of the proposed restriction. RAC supported, while taking into account the uncertainties, the proposed exposure scenario. RAC had general support for including substances restricted by CPR (Cosmetics Products Regulation) without traceable opinions of the Scientific Committee on Consumer Safety (SCCS). RAC supported the qualitative assessment of all substances with harmonised classification as carcinogenic (C) and mutagenic (M) Category 1A, 1B and 2 (except those classified only for inhalation route) are restricted in tattoo inks. RAC generally supported the approach for a (simple) quantitative assessment of all substances with harmonised classification as category repro 1A/B and 2 are restricted in tattoo inks.	**Rapporteurs** to prepare the second draft opinion, taking into account RAC-44 discussions, by beginning of May 2018
3) C9-C14 PFCAs, their salts and related substances The Rapporteurs presented and RAC discussed the first draft opinion.	

RAC agreed that the PBT/vPvB properties of the group of C9-C14 PFCAs and their salts are sufficient to justify the risk. Identified hazard RAC took note of the human health hazards of some of these substances but agreed that assessment of these endpoints is not necessary to demonstrate risk. Risk assessment either for human health and environment can be done only qualitatively. RAC concluded that C9-C14 PFCA-related substances are degraded to C9-C14 PFCAs in the environment, they need to be considered as PBT-substances. Exposure and emissions RAC concluded that properties of the PBT/vPvB substances lead to an increased uncertainty in the estimation of exposure to human health and the environment, the focus is therefore on the assessment of the releases. Even if uncertain, the release estimates provide a sufficient basis to conclude that current and potential future uses of C9-C14 PFCAs and related substances lead to releases. Risk characterisation Based on the PBT/vPvB properties and information on exposure and emissions, RAC agreed on the characterisation of the risks.	**Rapporteurs** to prepare the second draft opinion, taking into account RAC-44 discussions, by beginning of May 2018.
10. Authorisation	
10.1 General authorisation issues	
b) Update on incoming/future applications	
RAC noted the information presented by the Secretariat.	
10.2 Authorisation applications	
a) Discussion on key issues	
1. DBP_AVX **2. Diglyme_Omnichem** **3. SD_Olwerke** ECHA Secretariat presented the key issues in the applications for authorisation.	
b) Agreement on Draft Opinions	
1. CT_Hapoc (Use 1) RAC agreed on the draft opinion as proposed by the Rapporteurs.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and the review report as explained in the draft opinion. RAC agreed to give no advice to SEAC on the length of the review period.	**SECR** to send the draft opinion to the applicant for commenting.
2. CT_Hapoc_2 (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation as explained in the draft opinion. RAC agreed to give no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
3. CT_Hapoc_3 (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation as explained in the draft opinion. RAC agreed to give no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
4. SC_Wesco (1 use) **5. DtC_Wesco (1 use)** **6. PCO_Aviall (2 uses)** RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs described in the applications are not appropriate and	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicants for commenting.

effective in limiting the risk to workers and the general population. RAC decided to recommend additional conditions and monitoring arrangements for the authorisations and the review reports as explained in the draft opinions. RAC agreed to give no advice to SEAC on the length of the review period on the use of dichromium tris(chromate) and the Use 1 of penatzinc chromate octahydroxide in formulation of mixtures. RAC recommends to SEAC to consider a review period of no longer than seven years on the use of strontium chromate and the Use 2 of pentazinc chromate octahydroxide.	
7. PCO_IP (2 uses) RAC took note of the presentation by the Rapporteurs on the opinion development progress update.	**Rapporteurs** to develop draft opinions for the discussion and agreement at RAC-45 plenary meeting.
c) Adoption of final opinions	
-	
10.3 Review Reports	
b) Agreement on draft opinions	
1. RR1_DEHP_VINYLOOP (2 uses) **2. RR1_DEHP_PP (2 uses)** RAC took note and discussed the presentation by the Rapporteurs on the opinion development progress update.	**Rapporteurs** to consider RAC-44 discussion and to develop draft opinions for the discussion and agreement at RAC-45 plenary meeting.
11. AOB	
-	
12. Action points and main conclusions of RAC-44	
SECR to upload the adopted action points to CIRCA BC.	

Table 1: CLH opinions which were adopted at RAC-44

1. Octamethylcyclotetrasiloxane (D4)
2. Branched hexatriacontane
3. 2-methoxyethyl acrylate
4. Diisooctyl phthalate (DIOP)
5. Imiprothrin (ISO)
6. Silicon carbide (fibres fulfilling the WHO definition)
7. Pymetrozine (ISO)
8. Margosa extract
9. Ipconazole (ISO)
10. Ethofumesate (ISO)
11. Lactic acid
12. Di-"isononyl" phthalate (DINP)
13. Mefentrifluconazole
14. MCPA-thioethyl

1. Octamethylcyclotetrasiloxane; D4

Existing Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	014-018-00-1	Octamethylcyclotetrasiloxane; [D4]	209-136-7	556-67-2	Repr. 2 Aquatic Chronic 4	H361f*** H413	GHS08 Wng	H361f*** H413			
Dossier submitters proposal	014-018-00-1	Octamethylcyclotetrasiloxane; [D4]	209-136-7	556-67-2	**Retain** Repr. 2 **Modify** Aquatic Chronic 1	**Retain** H361f*** **Modify** H410	**Retain** GHS08 Wng **Add** GHS09	**Retain** H361f*** **Modify** H410		**Add** M=10	
RAC opinion	014-018-00-1	Octamethylcyclotetrasiloxane; [D4]	209-136-7	556-67-2	**Retain** Repr. 2 **Modify** Aquatic Chronic 1	**Retain** H361f*** **Modify** H410	**Retain** GHS08 Wng **Add** GHS09	**Retain** H361f*** **Modify** H410		**Add** M=10	
Resulting Annex VI entry if agreed by COM	014-018-00-1	Octamethylcyclotetrasiloxane; [D4]	209-136-7	556-67-2	Repr. 2 Aquatic Chronic 1	H361f*** H410	GHS08 Wng GHS09	H361f*** H410		M=10	

2. Branched hexatriacontane

Existing Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	601-064-00-8	branched hexatriacontane	417-070-7	151006-62-1	Aquatic Chronic 4	H413		H413			
Dossier submitters proposal	601-064-00-8	branched hexatriacontane	417-070-7	151006-62-1	**Remove** Aquatic Chronic 4	**Remove** H413		**Remove** H413			
RAC opinion	601-064-00-8	branched hexatriacontane	417-070-7	151006-62-1	**Remove** Aquatic Chronic 4	**Remove** H413		**Remove** H413			
Resulting Annex VI entry if agreed by COM	601-064-00-8	branched hexatriacontane	417-070-7	151006-62-1	Removal of the existing entry from Annex VI						

3. 2-methoxyethyl acrylate

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	2-methoxyethyl acrylate	221-499-3	3121-61-7	Flam. Liq. 3 Acute Tox. 4 Acute Tox. 3 Skin Corr. 1C Eye Dam. 1 Skin Sens. 1 Muta. 2 Repr. 1B	H226 H302 H331 H314 H318 H317 H341 H360FD	Dgr GHS 02 GHS 05 GHS 06 GHS 08	H226 H302 H331 H314 H317 H341 H360FD	EUH071		
RAC opinion	TBD	2-methoxyethyl acrylate	221-499-3	3121-61-7	Flam. Liq. 3 Acute Tox. 4 Acute Tox. 3 Skin Corr. 1C Eye Dam. 1 Skin Sens. 1 Muta. 2 Repr. 1B	H226 H302 H331 H314 H318 H317 H341 H360FD	Dgr GHS 02 GHS 05 GHS 06 GHS 08	H226 H302 H331 H314 H317 H341 H360FD	EUH071	oral; ATE = 404 mg/kg inhalation; ATE = 2.7 mg/L	
Resulting Annex VI entry if agreed by COM	TBD	2-methoxyethyl acrylate	221-499-3	3121-61-7	Flam. Liq. 3 Acute Tox. 4 Acute Tox. 3 Skin Corr. 1C Eye Dam. 1 Skin Sens. 1 Muta. 2 Repr. 1B	H226 H302 H331 H314 H318 H317 H341 H360FD	Dgr GHS 02 GHS 05 GHS 06 GHS 08	H226 H302 H331 H314 H317 H341 H360FD	EUH071	oral; ATE = 404 mg/kg inhalation; ATE = 2.7 mg/L	

4. Diisooctyl phthalate

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	diisooctyl phthalate	248-523-5	27554-26-3	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
RAC opinion	TBD	diisooctyl phthalate	248-523-5	27554-26-3	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
Resulting Annex VI entry if agreed by COM	TBD	diisooctyl phthalate	248-523-5	27554-26-3	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

5. Imiprothrin (ISO)

Existing Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-259-00-5	imiprothrin (ISO); reaction mass of: [2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-cis-chrysanthemate; [2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-trans-chrysanthemate	428-790-6	72963-72-5	Acute Tox. 4* Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410			
Dossier submitters proposal	613-259-00-5	imiprothrin (ISO); reaction mass of: [2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-cis-chrysanthemate; [2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-trans-chrysanthemate	428-790-6	72963-72-5	**Modify** Acute Tox. 4 **Add** Acute Tox. 4 Repr. 2 **Retain** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H302 H400 H410 **Add** H332 H361d	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H302 H410 **Add** H332 H361d		**Add** oral: ATE = 550 mg/kg bw inhalation: ATE = 1.4 mg/L M=10 (acute) M=10 (chronic)	
RAC opinion	613-259-00-5	imiprothrin (ISO); reaction mass of: [2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-cis-chrysanthemate; [2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-trans-chrysanthemate	428-790-6	72963-72-5	**Modify** Acute Tox. 4 **Add** Acute Tox. 4 Carc. 2 STOT SE 2 **Retain** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H302 **Add** H332 H351 H371 (nervous system; oral, inhalation) **Retain** H400 H410	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H302 H410 **Add** H332 H351 H371 (nervous system; oral, inhalation)		**Add** oral: ATE = 550 mg/kg inhalation: ATE = 1.4 mg/L M=10 (acute) M=10 (chronic)	
Resulting Annex VI	613-259-00-5	imiprothrin (ISO); reaction mass of:	428-790-6	72963-72-5	Acute Tox. 4 Acute Tox. 4	H302 H332	GHS07 GHS08	H302 H332		oral: ATE = 550 mg/kg bw	

entry if agreed by COM		[2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-cis-chrysanthemate; [2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-trans-chrysanthemate			Carc. 2 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H371 (nervous system; oral, inhalation) H400 H410	GHS09 Wng	H351 H371 (nervous system; oral, inhalation) H410		inhalation: ATE = 1.4 mg/L M=10 (acute) M=10 (chronic)	

6. Silicon carbide (fibres fulfilling the WHO definition)

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	silicon carbide (fibres fulfilling the WHO definition: diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1)	-	-	Carc. 1B	H350i	GHS08 Dgr	H350i			
RAC opinion	TBD	silicon carbide fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1)	206-991-8	409-21-2 308076-74-6	Carc. 1B	H350i	GHS08 Dgr	H350i			
Resulting Annex VI entry if agreed by COM	TBD	silicon carbide fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1)	206-991-8	409-21-2 308076-74-6	Carc. 1B	H350i	GHS08 Dgr	H350i			

7. Pymetrozine (ISO)

Existing Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-202-00-4	pymetrozine (ISO); (E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one		123312-89-0	Carc. 2 Aquatic Chronic 3	H351 H412	GHS08 Wng	H351 H412			
Dossier submitters proposal	613-202-00-4	pymetrozine (ISO); (E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one		123312-89-0	**Retain** Carc. 2 **Add** Repr. 2 **Modify** Aquatic Chronic 1	**Retain** H351 **Add** H361fd **Modify** H410	**Retain** GHS08 Wng **Add** GHS09	**Retain** H351 **Add** H361fd **Modify** H410		**Add** M=1	
RAC opinion	613-202-00-4	pymetrozine (ISO); (E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one		123312-89-0	**Retain** Carc. 2 **Add** Repr. 2 **Modify** Aquatic Chronic 1	**Retain** H351 **Add** H361fd **Modify** H410	**Retain** GHS08 Wng **Add** GHS09	**Retain** H351 **Add** H361fd **Modify** H410		**Add** M=1	
Resulting Annex VI entry if agreed by COM	613-202-00-4	pymetrozine (ISO); (E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one		123312-89-0	Carc. 2 Repr. 2 Aquatic Chronic 1	H351 H361fd H410	GHS08 GHS09	H351 H361fd H410		M=1	

8. Margosa, ext. [cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide]

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	Margosa, ext. [cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide]	283-644-7	84696-25-3	No classification and labelling						
RAC opinion	TBD	Margosa, ext. [cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide]	283-644-7	84696-25-3	Aquatic Chronic 3	H412	-	H412			
Resulting Annex VI entry if agreed by COM	TBD	Margosa, ext. [cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide]	283-644-7	84696-25-3	Aquatic Chronic 3	H412	-	H412			

9. Ipconazole (ISO)

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	603-RST-VW-Y	ipconazole (ISO); (1RS,2SR,5RS;1RS,2SR,5SR)-2-(4-chlorobenzyl)-5-isopropyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	-	-	Repr. 2 Acute Tox. 4 STOT RE 2 Aquatic Chronic 1	H361d H302 H373 (eyes, skin, liver, gastrointestinal tract) H410	GHS08 GHS07 GHS09 Wng	H361d H302 H373 (eyes, skin, liver, gastrointestinal tract) H410		M=100	
RAC opinion	603-RST-VW-Y	ipconazole (ISO); (1RS,2SR,5RS;1RS,2SR,5SR)-2-(4-chlorobenzyl)-5-isopropyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	-	-	Repr. 1B Acute Tox. 4 STOT RE 2 Aquatic Chronic 1	H360D H302 H373 (eyes, skin, liver) H410	GHS08 GHS07 GHS09 Dgr	H360D H302 H373 (eyes, skin, liver) H410		oral: ATE = 500 mg/kg bw M=100	
Resulting Annex VI entry if agreed by COM	603-RST-VW-Y	ipconazole (ISO); (1RS,2SR,5RS;1RS,2SR,5SR)-2-(4-chlorobenzyl)-5-isopropyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	-	-	Repr. 1B Acute Tox. 4 STOT RE 2 Aquatic Chronic 1	H360D H302 H373 (eyes, skin, liver) H410	GHS08 GHS07 GHS09 Dgr	H360D H302 H373 (eyes, skin, liver) H410		oral: ATE = 500 mg/kg bw M=100	

10. Ethofumesate (ISO)

Existing Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-314-00-2	ethofumesate (ISO); (RS)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate	247-525-3	26225-79-6	Aquatic Chronic 2	H411	GHS09	H411			
Dossier submitters proposal	607-314-00-2	ethofumesate (ISO); (RS)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate	247-525-3	26225-79-6	**Add** Aquatic Acute 1 **Modify** Aquatic Chronic 1	**Add** H400 **Modify** H410	**Retain** GHS09 **Add** Wng	**Modify** H410		**Add** M=1 M=1	
RAC opinion	607-314-00-2	ethofumesate (ISO); (RS)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate	247-525-3	26225-79-6	**Add** Aquatic Acute 1 **Modify** Aquatic Chronic 1	**Add** H400 **Modify** H410	**Retain** GHS09 **Add** Wng	**Modify** H410		**Add** M=1 M=1	
Resulting Annex VI entry if agreed by COM	607-314-00-2	ethofumesate (ISO); (RS)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate	247-525-3	26225-79-6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	

11. Lactic Acid

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	L-(+)-lactic acid; (2S)-2-hydroxypropanoic acid	201-196-2	79-33-4	STOT SE 3 Skin Irrit. 2 Eye Dam. 1	H335 H315 H318	GHS05 GHS07 Dgr	H335 H315 H318			
RAC opinion	TBD	L-(+)-lactic acid; (2S)-2-hydroxypropanoic acid	201-196-2	79-33-4	Skin Corr. 1C Eye Dam. 1	H314 H318	GHS05 Dgr	H314	EUH071		
Resulting Annex VI entry if agreed by COM	TBD	L-(+)-lactic acid; (2S)-2-hydroxypropanoic acid	201-196-2	79-33-4	Skin Corr. 1C Eye Dam. 1	H314 H318	GHS05 Dgr	H314	EUH071		

12. DINP

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	TBD	1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9-rich; [1] di-"isononyl" phthalate; [2] [DINP]	271-090-9 [1] 249-079-5 [2]	68515-48-0 [1] 28553-12-0 [2]	Repr. 1B	H360Df	GHS08 Dgr	H360Df			
RAC opinion	TBD	1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9-rich; [1] di-"isononyl" phthalate; [2] [DINP]	271-090-9 [1] 249-079-5 [2]	68515-48-0 [1] 28553-12-0 [2]	No classification and labelling						

13. Mefentrifluconazole

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole	-	1417782-03-6	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410		M=1 M=1	
RAC opinion	TBD	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole	-	1417782-03-6	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410		M=1 M=1	
Resulting Annex VI entry if agreed by COM	TBD	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole	-	1417782-03-6	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410		M=1 M=1	

14. MCPA-thioethyl

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	MCPA-thioethyl (ISO); S-ethyl (4-chloro-2-methylphenoxy)ethan ethioate; S-ethyl 4-chloro-o-tolyloxythioacetate	246-831-4	25319-90-8	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		M=10 M=10	
RAC opinion	TBD	MCPA-thioethyl (ISO); S-ethyl (4-chloro-2-methylphenoxy)ethan ethioate; S-ethyl 4-chloro-o-tolyloxythioacetate	246-831-4	25319-90-8	Acute Tox. 4 STOT RE. 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H373 (liver) H400 H410	GHS07 GHS08 GHS09 Wng	H302 H373 (liver) H410		oral: ATE = 450 mg/kg bw M=10 M=10	
Resulting Annex VI entry if agreed by COM	TBD	MCPA-thioethyl (ISO); S-ethyl (4-chloro-2-methylphenoxy)ethan ethioate; S-ethyl 4-chloro-o-tolyloxythioacetate	246-831-4	25319-90-8	Acute Tox. 4 STOT RE. 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H373 (liver) H400 H410	GHS07 GHS08 GHS09 Wng	H302 H373 (liver) H410		oral: ATE = 450 mg/kg bw M=10 M=10	

Table 2: CLH opinions which are postponed to RAC-45

1. Granulated copper
2. Nitric Acid …%

1. Granulated copper

No current Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	Granulated copper	231-159-6	7440-50-8	Eye Irrit. 2[8] Aquatic Chronic 2	H319 H411	GHS07 GHS09	H319 H411			
RAC opinion	TBD	Granulated copper	231-159-6	7440-50-8							
Resulting Annex VI entry if agreed by COM	TBD	Granulated copper	231-159-6	7440-50-8							

[8] Hazard classes highlighted in grey were agreed in RAC-44 and are not subject for discussion in RAC-45.

2. Nitric acid…%

Existing Annex VI entry (CLP, Table 3.1)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	007-004-001	nitric acid ... %	231-714-2	7697-37-2	Ox. Liq. 3 Skin Corr. 1A	H272 H314	GHS03 GHS05 Dgr	H272 H314		Ox. Liq. 3; H272: ≥ 65% Skin Corr. 1A; H314: C ≥ 20 % Skin Corr. 1B; H314: 5 % ≤ C < 20 %	B
Dossier submitters proposal	007-004-001	nitric acid …% [C > 70 %]	231-714-2	7697-37-2	**Add** Acute Tox. 1	**Add** H330	**Add** GHS06	**Add** H330	**Add** EUH071	[Ox. Liq. 2; H272: ≥ 99% Ox Liq. 3: 65% ≤ C < 99%][9]	
Dossier submitters proposal	TBD	nitric acid …% [C ≤ 70 %]	231-714-2	7697-37-2	**Add** Acute Tox. 3	**Add** H331	**Add** GHS06	**Add** H331	**Add** EUH071	**Add** Ox Liq. 3: ≥ 65% inhalation: ATE = 2.1 mg/L/4hr	
RAC opinion	007-004-00-1	nitric acid …% [C > 70 %]	231-714-2	7697-37-2							
RAC opinion	TBD	nitric acid …% [C ≤ 70 %]	231-714-2	7697-37-2							
Resulting Annex VI entry if agreed by COM	007-004-00-1	nitric acid …% [C > 70 %]	231-714-2	7697-37-2							
Resulting Annex VI entry if agreed by COM	007-004-00-1	nitric acid …% [C ≤ 70 %]	231-714-2	7697-37-2							

[9] In 2012 the German CA submitted a proposal to ECHA to supplement the current classification of nitric acid by adding new classification as Acute Tox. 1; H330 with the supplemental hazard information EUH071 (Corrosive to the respiratory tract) and a change of the current classification as oxidizing liquid Category 3 to oxidising liquid Category 2; H272 for concentrated nitric acid (C ≥ 99 %). At RAC-24 this was agreed. DE later asked COM to postpone the inclusion in an ATP due to new data, which lead up to this new proposal where the current entry is split into two; above and below 70%. The SCLs for Ox. Liq. are hence already agreed by RAC.

Part III. List of Attendees of the RAC-44 meeting

RAC Members
Agapiou Agapios
Andreou Kostas
Aquilina Gabriele
Baranski Boguslaw
Biró Anna
Bjørge Christine
Borg Daniel
Branisteanu Radu
Carvalho João
Chankova-Petrova Stephka
Czerczak Slawomir
de la Flor Tejero Ignacio
Dunauskiene Lina
Dungey Stephen
Geoffroy Laure
Gruiz Katalin
Hakkert Betty
Husa Stine
Ilie Mihaela
Kadikis Normunds
Karadjova Irina
Leinonen Riitta
Losert Annemarie
Lund Bert-Ove
Martinek Michal
Menard Srpčič Anja
Moeller Ruth
Mullooly Yvonne
Murray Brendan
Neumann Michael
Paris Pietro
Polakovicova Helena
Printemps Nathalie
Pronk Marja
Rucki Marian
Rupprich Norbert
Santonen Tiina
Schlüter Urs
Schulte Agnes
Seba Julie
Smith Andrew
Soerensen Hammer Peter
Sogorb Miguel A.
Spetseris Nikolaos
Stahlmann Ralf
Tobiassen Lea Stine
Tsitsimpikou Christina
Užomeckas Žilvinas
Varnai Veda
RAC co-opted members
Chiurtu Elena-Ruxandra
Jankowska Elzbieta
van der Haar Rudolf
Viegas Susana

Apologies, Members
Agapiou Agapios
Andreou Kostas
Kapelari Sonja
Members' advisers
Beetstra Renske (Betty Hakkert)_AfA DEHP
Esposito Dania (Pietro Paris)
Kuittinen Marko (Riitta Leinonen)
Kupczewska-Dobecka Malgorzata (Slawomir Czerczak)
Mahiout Selma (Tiina Santonen)
Peczkowska Beata (Boguslaw Baranski)
Romoli Debora (Pietro Paris)
Talasniemi Petteri (Riitta Leinonen)
Uuksulainen Sanni (Tiina Santonen)
Commission
Blass-Rico Ana Maria (DG GROW)
Luvara Giuseppina (DG ENV)
Podniece Zinta (DG EMPL)
van der Jagt Katinka (DG ENV)
Regular stakeholder observers
Annys Erwin (CEFIC)
Barry Frank (ETUC)
Bernard Alice (ClientEarth)
Romano Mozo Dolores (EEB)
Rowe Rocky (ECPA)

Verougstraete Violaine (Eurometaux)
Waeterschoot Hugo (Eurometaux)
Apologies, stakeholders
Munari Tomaso (EuCheMs)
Occasional stakeholder observers
de Kort Patrick (EuPC)_CLH DINP
de Matos Olivier (Ecetoc)_CLH, DINP, D4
Gennart Jean-Philippe (Concawe)_Art 77(3)c
Sevenster Arjen (VinylPlus)_CLH DINP
Tillieux Geoffroy (EuPC)_CLH DIOP
Stakeholder experts
Andrew David (ECPA), CLH MCPA Thioethyl ester
Baken Stijn (Eurometaux), CLH granulated copper
Bjorgan Marie (Cefic), CLH Nitric acid
Boogaard Peter (Cefic), Art 77(3)c Benzene
Clarius Tom (Cefic), CLH Silicon carbide
Cromie Ruth (UNEP/AEWA), restriction Lead in shot
Fischer Hendrik (VinylPlus), CLH DINP
Kelly Graig (Cefic), Art 77(3)c Acrylonitrile
Lloyd Sara (ECPA)_Syngenta_CLH Pymetrozine
Mackie Carol (Cefic), CLH granulated copper
Oller Adriana (Eurometaux), Art 77 (3)c Nickel and its compounds
Otter Rainer (Ecetoc), CLH DINP
Palermo Christine (Cefic), CLH DINP, DIOP
Plotzke Kathy (Cefic), CLH Octamethylcyclot extrasilixilane (D4)

Sarginson Nigel (EuPC), CLH DINP, DIOP	Luit Richard_Rest: tattoo inks
Scallan David (Cefic), restriction Lead in shot	
Stinchcombe Stefan (ECPA), CLH Mefentrifluconazole	**Commission**
Tesh John (ECPA), CLH Ipconazole	Bertato Valentina
Williams Steve (Concawe), Art 77(3)c Benzene	Garcia Enrique
Yamada Tomoya (ECPA)_Sumitomo_CLH Imiprothrin	
	EFSA
International organisation observer	Court Marques Daniele
Mikander Nina (OECD/UN)_restriction Lead in shot	Parra Morte Juan Manuel
REMOTE PARTICIPANTS	**Consultants for Art 77(3)c Acrylonitrile (WCA Consultancy)**
RAC Members	Bevan Ruth
Kapelari Sonja	Green Owen
Losert Annemarie	Rumsby Paul
Neumann Michael	Stutt Ed
Paris Pietro	
	Dossier submitters
Members' advisers	Andersen Trine Thorup_DK_CLH: DINP
Guichelaar Samantha (adviser to Marja Pronk)_CLH imiprothrin	Bernauer Ulrike_DE_CLH: nitric acid
Groothuis Floris (adviser to Marja Pronk)_CLH granuated copper	Boberg Julie_DK_CHL: DINP
Hölzl Christine (adviser to Annemarie Losert)_rapporteur for CLH margosa	Chion Béatrice_FR_CLH: granulated copper
Martin Theresa (adviser to Ralf Stahlmann)_DINP	Charles Sandrine_FR_CLH:2-MEA, DIOP, granulated copper
	Dominiak Dorota_PL_CLH: MCPA-thioethyl
SEAC rapporteurs	Frein Daniel_DE_CLH: margosa,
Anastasiou Christos_AfA: SD_Olwerke	Juśko Katarzyna_PL_CLH: MCPA thiotethyl
Brignon Jean-Marc_Rest: tattoo inks	Lerche Dorte_DK_PFCAs
Fankhauser Simone_AfA: DEHP	Mueller Andre_NL_CLH: silicon carbide
Fock Lars_DE_Rest: C9-C14 PFCAs	Niederstrasser Bernd_DE_Rest: C9-C14 PFCAs and tattoo inks

Oystein Fotland Tor_NO_Rest: tattoo inks
Staude Claudia_DE_Rest: C9-C14 PFCAs_CLH: D4
Trubiroha Achim_DE_Rest: tattoo inks
Van der Hagen Marianne_NO_Rest: tattoo inks
ECHA staff
Berges Markus
Blainey Mark
Bowmer Tim, Chairman
Broeckaert Fabrice
Clenaghan Conor
Dvorakova Dana
Ericsson Gunilla
Hollins Steve
Jaagus Triin
Jones Stella
Karjalainen Antti
Karjalainen Ari
Kivelä Kalle
Kokkola Leila
Kouloumpos Vasileios
Lapenna Silvia
Liopa Elīna
Logtmeijer Christiaan
Ludborzs Arnis
Luschutzky Evita
Mazzolini Anna
Mushtaq Fesil
Müller Gesine
Nicot Thierrry
Nygren Jonas

Orispää Katja
O´Rourke Regina
Pennese Daniele
Perazzolo Chiara
Pillet Monique
Prevedouros Konstantinos
Regil Pablo
Reuter Ulrike
Rheinberger Christoph
Rodriguez Iglesias Pilar
Roggeman Maarten
Simoes Ricardo
Spjuth Linda
Stoyanova Evgenia
Tanarro Celia
Uphoff Andreas
Väänänen Virpi

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-44 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-44 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-44 meeting

ANNEX IV Administrative issues and information items

27 February 2018
RAC/A/44/2018

Final Agenda
44th meeting of the Committee for Risk Assessment

27 February – 9 March 2018

ECHA Conference Centre (Annankatu 18, Helsinki)

Tuesday 27 February starts at 14.00
Friday 9 March ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/44/2018
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests

RAC/44/2017/01
(restricted)
Room document
For agreement

Item 5 – Report from other ECHA bodies and activities

a) Report on RAC 43 action points, written procedures and update on other ECHA bodies

RAC/44/2017/02
Room document
For information

b) RAC workplan for all processes

For information

c) General RAC procedures

RAC/44/2018/03
For discussion/agreement

Item 6 – Requests under Article 77(3)(c)

6.1 General occupational exposure issues

a) Feedback from the preparatory workshop on OEL

For information

6.2 Occupational exposure limits - opinion development

a) Nickel and its compounds
b) Benzene
c) Acrylonitrile

For adoption

Item 7 – Requests under Article 95 (3)

None

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

8.2 CLH dossiers

A. Hazard classes for agreement without plenary debate (fast-track)

2-methoxyethyl acrylate: physical hazards (flammable liquids), acute toxicity (all routes of exposure), skin corrosion, eye damage, respiratory / skin sensitisation

imiprothrin (ISO): acute toxicity (all routes of exposure), STOT RE, germ cell mutagenicity, environmental hazards

granulated copper: physical hazards, acute toxicity (all routes of exposure), STOT SE, skin irritation, skin sensitisation, STOT RE, germ cell mutagenicity, carcinogenicity, toxicity to reproduction

nitric acid…%: EUH071 (corrosive to the respiratory tract)

pymetrozine (ISO): environmental hazards

margosa, ext. [cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide]: acute toxicity (dermal and inhalation), skin/eye irritation, skin sensitisation, STOT SE, serious eye damage/irritation, germ cell mutagenicity, carcinogenicity

ipconazole (ISO): physical hazards, acute toxicity (all routes of exposure), STOT SE, serious eye damage / eye irritation, skin corrosion / irritation, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, environmental hazards

L-(+)-lactic acid: physical hazards, acute toxicity (all routes of exposure), skin sensitisation, STOT RE, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, environmental hazards

mefentrifluconazole: physical hazards (except explosives, self-reacting substances and oxidising solids), acute toxicity (dermal and inhalation), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, environmental hazards

B. Hazard classes for agreement with plenary debate

17) octamethylcyclotetrasiloxilane
18) branched hexatriacontane
19) 2-methoxyethyl acrylate
20) diisooctyl phthalate
21) imiprothrin (ISO)
22) silicon carbide (fibres fulfilling the WHO definition: diameter <3 µm, length > 5 µm and aspect ratio ≥ 3:1)
23) Granulated copper
24) nitric acid…%
25) pymetrozine (ISO)
26) Margosa, ext. [cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide]
27) ipconazole (ISO)
28) ethofumesate (ISO) (±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate
29) L-(+)-lactic acid; (2S)-2-hydroxypropanoic acid
30) 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9-rich; [1] di-"isononyl" phthalate; [2] (DINP)
31) (2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole
32) MCPA-thioethyl (from RAC 43)

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

a) Opinion development
   1) Lead and lead compounds in shot – final draft opinion

For adoption

2) Substances used in tattoo inks and permanent make-up – first draft opinion
3) C9-C14 PFCAs, their salts and related substances– first draft opinion

For discussion/agreement

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications

For information

10.2. Authorisation applications

a) Discussion on key issues
   4. DBP_AVX
   5. Diglyme_Omnichem
   6. SD_Olwerke

For discussion

b) Agreement on draft opinions

   1. CT_Hapoc (1 use)
   2. CT_Hapoc_2 (1 use)
   3. CT_Hapoc_3 (1 use)

RAC/44/2018/04
(Restricted)
For information

   4. DtC_Wesco (1 use)
   5. SC_Wesco (1 use)
   6. PCO_Aviall (2 uses)

For discussion and agreement

   7. PCO_IP (2 uses)

For discussion

c) Adoption of final opinions

No opinions to be finalised at this meeting.

For discussion and adoption

10.3. Review reports

c) Discussion on key issues

No review reports received for the key issues discussion

For discussion

d) Agreement on draft opinions
   1. RR1_DEHP_VINYLOOP (2 uses)
   2. RR1_DEHP_PP (2 uses)

For discussion

Item 11 – AOB

Item 12 – Action points and main conclusions of RAC-44

Table with Conclusions and Action points from RAC-44

For adoption

Annex II (RAC 44)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 44 meeting.

Document number	Title
RAC/A/44/2018	Final Draft Agenda
RAC/A/44/2018 Restricted	Draft outline agenda
RAC/44/2018/01 Restricted room document	Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95 (3) requests and Article 77 (3) requests
RAC/44/2018/02	Report on RAC-43 action points, written procedure and update on other ECHA bodies
RAC/44/2018/03	Appointment of co-opted members to RAC and SEAC
RAC/44/2018/04 Restricted document	Authorisation applications: Agreement on draft opinions – CT_Hapoc

ANNEX III (RAC-44)

The following participants, including those for whom the Chairman declared the interest on their behalf, declared potential conflicts of interest with the Agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLÜTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Harmonised classification & labelling		
MCPA-thioethyl (ISO)	Boguslaw BARANSKI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
Requests under Article 77(3) (c)		
Nickel and its compounds	-	-
Benzene	-	-
Acrylonitrile	-	-
Restrictions		
Tattoo inks	Christine BJØRGE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Tattoo inks	Peter Hammer SØRENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Tattoo inks	Stine HUSA	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		substance - no other mitigation measures applied.
Tattoo inks	Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
Tattoo inks	Agnes SCHULTE	Working for the CA which has been involved in the preparation of the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Tattoo inks	Urs SCHLÜTER	Working for the CA which has been involved in the preparation the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
PFCAs	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
	Daniel BORG	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
PFCAs	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
PFCAs	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
PFCAs	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		substance - no other mitigation measures applied.
PFCAs	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW		
Article 77.3(c)		
-	-	-
Restrictions		
-	-	-
Applications for Authorisation		
-	-	-
Harmonised classification & labelling		
1) Octamethylcyclotetrasiloxilane, D4 **2) Nitric acid ...%** **3) Pymetrozine (ISO)** **4) Margosa, ext. [cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical CO2]** **5) L-(+)-lactic acid** **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement (1-5).
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement (1-5).
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement (1-5).
	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement in (2) nitric acid, not in other dossiers.
1) Branched hexatriacontane **2) Imiprothrin (ISO)**	Andrew SMITH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
3) Ipconazole **4) Mefentrifluconazole** **UK**		measures applied. No personal involvement in (1 and 4); personal involvement in (2) and (3)
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement in (2) and (3).
1) 2-methoxyethyl acrylate **2) Diisooctyl phthalate (DIOP)** **3) Granulated copper** **FR**	Nathalie PRINTEMPS	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
silicon carbide (fibres fulfilling the WHO definition: diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) **NL**	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
ethofumesate (ISO) (±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate **AT**	Christine HÖLZL	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Annemarie LOSERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9- rich; [1]	Peter HAMMER SØRENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
di-"isononyl" phthalate; [2] [DINP] **DK**	Lea STINE TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

Helsinki, 21 February 2018

RAC/44/2018/02

ROOM DOCUMENT

44TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

27 February – 2 March 2018
and
6 – 9 March 2018

Helsinki, Finland

Concerns:	**Administrative issues and information items**
Agenda Point:	**5a**
Action requested:	**For information**

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-43 Action Points

The RAC-43 action points due for RAC-44 are completed.

2 Outcome of written procedures & other consultations

2.1 Written procedures for adoption of RAC opinions / minutes of the meeting

Opinions / minutes adopted via written procedure	Deadline	Report on the outcome
Written procedure for adoption of the minutes of RAC-43	19 February 2018	closed

2.2 RAC consultations (status by 21 February 2018)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
octamethylcyclotetrasiloxilane, (D4)	7 February 2018	closed
branched hexatriacontane	7 February 2018	closed
2-methoxyethyl acrylate	7 February 2018	closed
diisooctyl phthalate (DIOP)	5 February 2018	closed
imiprothrin (ISO)	7 February 2018	closed
silicon carbide (fibres fulfilling the WHO definition: diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1)	12 February 2018	closed
granulated copper	9 February 2018	closed
nitric acid…%	5 February 2018	closed
pymetrozine (ISO)	7 February 2018	closed
margosa, ext. [cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide]	7 February 2018	closed
ipconazole (ISO)	7 February 2018	closed
ethofumesate (ISO) (±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate	7 February 2018	closed
L-(+)-lactic acid; (2S)-2-hydroxypropanoic acid	7 February 2018	closed
1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9-rich; [1] di-"isononyl" phthalate; [2] (DINP)	9 February 2018	closed

Subject / document	Deadline	Status / follow-up
(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole	7 February 2018	closed
MCPA-thioethyl (ISO) (DL extended)	6 February 2018	closed
Application for Authorisation		
CT_Hapoc_2 Consultation on draft opinion	14 February 2018	closed
CT_Hapoc_3 Consultation on draft opinion	14 February 2018	closed
PCO_Aviall Consultation on draft opinions	14 February 2018	closed
DtC_Wesco Consultation on draft opinion	14 February 2018	closed
SC_Wesco Consultation on draft opinion	14 February 2018	closed
CT_Hapoc Consultation on draft opinions	15 February 2018	closed
SD_Olwerke Consultation on application	4 April 2018	open
Diglyme_Omnichem Consultation on application	4 April 2018	open
DBP_AVX Consultation on application	4 April 2018	open
RAC-Working Procedure on carcinogenicity dose-response relationships and DNEL settings for threshold substances, including reprotoxic properties.	19 February 2018	closed
Restrictions		
Consultation on third draft opinion on lead in shot	14 February 2018	closed
Art. 77. 3. c request on evaluations OELs		
Nickel and its compounds	14 February 2018	closed
Benzene	14 February 2018	closed
Acrylonitrile	14 February 2018	closed

2.3 Other written consultations of RAC (status by 21 February 2018)

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-43	19 January 2018	closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
No call		
Application for Authorisation		
Call for expression of interest in rapporteurship on applications for authorisation on SVHCs in 12 new entries in Annex XIV of the REACH Regulation. Full list of the new entries is published in Annex of the Commission Regulation (EU) 2017/999[10].		
Restriction Call for expression of interest in rapporteurship for rubber granulates restriction dossier	19 January – 15 February 2018	Three volunteers expressed their interest

2.5 Written procedures for the appointment of (co-)rapporteurs

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling - no written procedures			
Applications for Authorisation– no written procedures			
Restrictions – no written procedures			

2.6 Follow-up on the opinions on applications for authorisation adopted by RAC and SEAC

Opinion(s)	Sent on
Opinions sent to the European Commission, the Member States and applicants	
EDC_Olon (2 opinions)	7 November 2017
Diglyme_Acton (2 opinions)	24 November 2017
MOCA_Reachlaw (1 opinion) SC_Aviall (2 opinions) CT_Haas (1 opinion) SD_Haas (1 opinion) PD_Haas (1 opinion)	15 December 2017
PC_SC_Saes (2 opinions)	25 January 2018
EDC_Microbeads (1 opinion)	31 January 2018

[10] Commission Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)